No. 24-3528

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

GEORGE BEITZEL, KATHERINE KRAIG, and SHARON GOLDSTEIN, on behalf of themselves and all others similarly situated,

Plaintiffs-Appellants,

v.

XAVIER BECERRA, SECRETARY OF HEALTH & HUMAN SERVICES,

Defendant-Appellee.

On Appeal from the United States District Court
for the Eastern District of California
No. 2:23-cv-01932-WBS-DB
Hon. William B. Shubb

BRIEF OF APPELLANTS

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INTRODUCTION

Plaintiffs-Appellants are Medicare beneficiaries who for years received coverage of an injectable drug, administered by health care professionals in outpatient clinical settings. Medicare then pulled the rug out from under them when, without notice, it stopped covering the drug as it had been, allowing Plaintiffs to be charged its full, astronomically high cost. Plaintiffs bring this proposed class action claiming that the Due Process Clause and the Medicare Act require procedural safeguards when Medicare abruptly changes the coverage terms of a drug as it did for them. They challenge the Defendant's policy and practice of affording Medicare beneficiaries no procedural protections at all.

George Beitzel, 85, Sharon Goldstein, 81, and Katherine Kraig, 73, require ustekinumab (brand name Stelara) to control symptoms of their serious medical conditions. Medicare's outpatient benefit, Part B, covered Plaintiffs' drug as a medication furnished "incident to" a physician's or other practitioner's service. The Defendant Secretary of Health and Human Services ("Secretary"), acting through Medicare contractors, then decided that as of October 15, 2021, Part B would no longer cover Stelara as "incident to" a physician's service because under agency guidelines it was determined to be "usually self-administered by the patient." The drug was still covered by Medicare under its prescription drug benefit, known as Part D. Had Plaintiffs received advance notice, they could have

planned accordingly and made arrangements to avoid any interruptions in their coverage or treatment. But, pursuant to the Secretary's policy and practice, no advance notice of the change in coverage terms was required for beneficiaries, even if they had previously received Part B coverage for the drug. Unaware of the change, Plaintiffs continued to receive scheduled injections for several months from their usual providers. Plaintiffs only learned of the non-coverage by Part B when, well after the injections occurred, they received routine, mailed statements listing denied claims. Those notices stated that they could be billed extremely high dollar amounts for each injection, over $43,000 for each of Beitzel's four doses, for example.

Plaintiffs tried appealing these determinations using Medicare's administrative appeal system, but they received decisions stating that no advance notice of non-coverage was required, and that they were responsible for the bills. No protections existed for them. Plaintiffs face ongoing financial liability and other harm from the Secretary's policies. Kraig suffered a severe medical relapse when she could not access Stelara for a time. Goldstein's provider referred her bill to a debt collection agency. Beitzel, who now relies on a friend to inject the drug since Parkinson's disease prevents him from self-administering, was blindsided by the change in coverage rules and also scrambled to make alternate arrangements.

By any objective standard, this is shocking and unfair. As a federal program, Medicare is subject to constitutional due process requirements. Medicare also has built-in safeguards to protect beneficiaries from unexpected non-coverage. Yet it is the Secretary's official policy that beneficiaries are not entitled to advance notice or to liability protections when he makes this type of change in how a drug is covered.

Plaintiffs challenged this policy on behalf of themselves and a class of those who are similarly situated, seeking declaratory and injunctive relief that would require the Secretary to amend his practices. The district court dismissed pursuant to Rules 12(b)(1) and 12(b)(6). But contrary to the court's conclusions, it had subject matter jurisdiction over all of Plaintiffs' claims, they have standing for all of the relief they seek, and they adequately alleged due process and statutory claims. This Court should reverse.

JURISDICTIONAL STATEMENT

1. Plaintiffs alleged that the district court had jurisdiction pursuant to 42 U.S.C. § 405(g), as incorporated into the Medicare statute by 42 U.S.C. §§ 1395ff(b)(1)(A) and 1395w-22(g)(5). ER-20.[1] Jurisdiction was contested partially for Beitzel and in full for Kraig and Goldstein.

2. The judgment from which this appeal is taken is final and disposes of

[1] On appeal, Plaintiffs do not pursue the alternative bases for jurisdiction they alleged.

all of Plaintiffs' claims. ER-3, ER-4–6. This Court has appellate jurisdiction pursuant to 28 U.S.C. § 1291.

3. The district court entered its decision granting Defendant's motion to dismiss on April 22, 2024, and entered the judgment from which this appeal is taken on May 24, 2024. ER-3. Plaintiffs filed a timely notice of appeal on June 3, 2024. ER-53; Fed. R. App. P. 4(a)(1)(B).

STATUTORY AUTHORITIES

Relevant legal authorities appear in the Addendum to this brief.

ISSUES PRESENTED

1. Whether the district court has jurisdiction pursuant to 42 U.S.C. § 405(g) over Plaintiffs' claims challenging systemic policies that cannot be remedied through individual administrative appeals.

2. Whether Plaintiffs have Article III standing to seek prospective injunctive relief, including for alleged procedural violations.

3. Whether Plaintiffs adequately pleaded a due process claim where they alleged that the Secretary changed the eligibility criteria for Medicare prescription drug coverage without adequate notice.

4. Whether Plaintiffs plausibly alleged that the Secretary violated the Medicare Act by failing to apply its liability protection provisions.

STATEMENT OF THE CASE

A. Legal Framework

1. Medicare Drug Coverage Under Parts B and D

Established in 1965 as Title XVIII of the Social Security Act, Medicare is the federal health insurance program for individuals at least age 65 or who have certain disabilities. 42 U.S.C. §§ 1395 *et seq*. The Secretary is charged with the overall administration of Medicare through the Centers for Medicare and Medicaid Services ("CMS"). *Id*. § 1395kk. Medicare consists of four "Parts," two of which—Parts B and D—are particularly relevant to this case. Under Part A, beneficiaries are entitled to coverage for inpatient care, such as hospital and nursing facility services. *Id*. § 1395d(a). Part B covers physician office visits as well as other outpatient services. *Id*. § 1395k(a). Under Part C, beneficiaries opt to receive coverage through privately-administered "Medicare Advantage" plans instead of directly from the traditional Medicare program (Parts A and B). *Id*. § 1395w-21(a). With a few exceptions not relevant here, Medicare Advantage plans must cover all items and services for which benefits are available under traditional Medicare. *Id*. §§ 1395w-22(a)(1)(A)-(B).

Part D is an outpatient prescription drug benefit. *Id*. §§ 1395w-101 *et seq*. Under this benefit, individuals receive coverage of medically necessary drugs by

enrolling in a stand-alone, private prescription drug plan, or in a Medicare Advantage plan that includes prescription drug coverage. *Id.* §§ 1395w-101–w-102. Each of these Part D plans has its own "formulary" or list of covered drugs, as well as prior authorization requirements and a network of approved pharmacies. These plan-specific coverage requirements are subject to exception, and denials of exceptions may be appealed by the enrollee. ER-23–24, ¶¶ 26–27.

Although Part D covers most outpatient prescription drugs, Medicare Part B covers some outpatient drugs, typically those that are injected or infused in physicians' offices or other outpatient clinical settings. 42 U.S.C. § 1395x(s)(2)(A). Part B pays for these drugs when they are furnished "incident to the service of a physician (or other practitioner)," 42 C.F.R. § 410.26(b); *see also* 42 U.S.C. § 1395x(s)(2)(A); Medicare Benefit Policy Manual, Pub. 100-02 ("MBPM"), Ch. 15 § 50.

2. Coverage of "Self-Administered Drugs"

For Medicare Part B to pay for a drug furnished "incident to" a physician's service, the drug must be one that is "not usually self-administered by the patient." 42 U.S.C. § 1395x(s)(2)(A). CMS interprets "usually" to mean "more than 50 percent of the time for all Medicare beneficiaries who use the drug." MBPM Ch. 15 § 50.2.C. CMS directs its regional Medicare Administrative Contractors ("MACs") that handle Part B claims to use statistical information or certain

presumptions and other medical information to determine whether a drug will be considered "usually self-administered." *Id.*; *see also id.* § 50.2.A. CMS interprets "by the patient" to mean "Medicare beneficiaries as a collective whole." *Id.* § 50.2.E. It directed MACs to "make[] this determination on a drug-by-drug basis, not on a beneficiary-by-beneficiary basis." *Id.*

MACs must report to CMS the list of drugs they determine are excluded from Part B coverage because they are "usually self-administered." *Id.* § 50.2.I; ER-25–26, ¶ 36. CMS expects MACs to update these Self-Administered Drug Lists ("SAD Lists") at least annually. *Id.* Under a provision titled "*Provider* Notice of Noncovered Drugs," CMS also directs MACs to publish a list of the injectable drugs that are subject to the self-administered drug exclusion on their website at least 45 days prior to the date the drugs will not be covered by Part B. *Id.* § 50.2.G (emphasis added). Each of the 12 MAC jurisdictions for Part B claims maintains its own SAD List. ER-26, ¶ 37. Their lists are often similar, but not identical. 88 Fed. Reg. 52262, 52387 (Aug. 7, 2023). The SAD Lists are published as "Local Coverage Articles" on CMS's website. The Amended Complaint references and provides a link to Local Coverage Article A53032, which governed Beitzel's and Goldstein's claims. ER-26, ¶ 37; *see also, e.g.,* ER-33, ¶ 70; ER-40, ¶ 106.[2] Kraig's

[2] Local Coverage Article A53032 is contained in the Addendum to this brief and is available at: https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=53032.

claims were denied pursuant to Local Coverage Article A53021. ER-38, ¶¶ 94–95.

CMS has explained that when a drug is put on a SAD List and can no longer be covered under Part B, it is "almost always covered by Medicare Part D prescription drug coverage." 88 Fed. Reg. at 52387; ER-26, ¶ 38. However, it will be subject to the requirements of individual Part D plans, such as formularies, prior authorizations, and pharmacy networks. *See supra* p. 6. Thus, obtaining coverage can be a multi-step process, especially if the drug requires prior authorization or formulary exceptions. ER-47, ¶ 136 (in 2023, only 66% of Part D enrollees were in plans with Stelara on their formularies and all of those with formulary coverage had to obtain prior authorization before their plan would pay for it). In short, beneficiaries require time and information if they are to secure coverage of drugs determined to be self-administered without experiencing interruptions in coverage or treatment.

3. Protections for Medicare Beneficiaries

Beneficiaries in traditional Medicare receive a Medicare Summary Notice ("MSN") showing items and services that their providers billed to Medicare during the past three-month period (if the notice is sent by mail) or the past month (if the notice is sent electronically). ER-27, ¶ 41. The MSN shows what Medicare paid for each service and the amount the provider may bill the beneficiary, typically a deductible or coinsurance amount. If Medicare denies payment for items or

services listed on an MSN, beneficiaries may challenge those denials using the multi-level administrative appeal system.[3] ER-27, ¶¶ 41–42; 42 U.S.C. § 1395ff(b).

Medicare also has "limitation on liability" provisions that shield beneficiaries from the cost of non-covered care in certain circumstances. Thus, when beneficiaries administratively appeal a denial of coverage, two decisions are potentially made: (1) whether the item or service can be covered by Medicare, and (2) if it is not covered, who is liable for the bill. Under the statute and for purposes of this case, beneficiaries' financial liability is waived when (1) coverage is denied because the care was not reasonable and necessary, and (2) the beneficiary did not know, and could not reasonably have been expected to know, that Medicare would not cover the service in question. 42 U.S.C. § 1395pp(a); ER-27–28, ¶ 43; *see also* Medicare Managed Care Manual, Pub. 100-16 ("MMCM"), Ch. 4 § 160.

CMS gauges beneficiaries' knowledge of non-coverage by whether they receive advance written notice that the services subject to liability protection are not covered. The notice can be given by Medicare contractors or by medical providers. ER-28, ¶ 45; 42 C.F.R. §§ 411.404(b)–(c). As explained by CMS, "written notice allows the beneficiary to . . . make an informed decision whether or not to receive the item and/or service, and . . . better participate in his/her own

[3] Medicare Advantage enrollees similarly receive statements and can appeal denied claims. ER-27, ¶¶ 41–42; 42 U.S.C. § 1395w-22(g).

health care treatment decisions." Medicare Claims Processing Manual, Pub. 100-4 ("MCPM"), Ch. 30 § 40. CMS provides specifications for written notice, including a "timeliness" requirement. *Id*. §§ 40.2, 40.2.1. Written notice "[m]ust be issued far enough in advance of an event (e.g. receiving a medical service) so that the beneficiary can make a rational, informed decision without undue pressure." *Id*. § 40.2.1.A. CMS has issued a model Advance Beneficiary Notice of Non-Coverage ("ABN") that contains the required information. ER-28, ¶¶ 46–47; MCPM Ch. 30 § 50.5. Medicare Advantage enrollees have similar protections. ER-29, ¶ 48; MMCM Ch. 4 § 160.

Legislative history indicates that Congress did not intend these provisions to apply to "*clearly* noncovered services such as . . . eyeglasses . . . hearing aids . . . [or] routine dental services," which Medicare has *never* covered. S. Rep. No. 92-1230, 92d Cong., 2d Sess. 295 (1972) (emphasis added); ER-29, ¶ 49. In these situations, a presumption can be made that "the beneficiary . . . was aware, or should have been aware, of the fact that the services were not covered." *Id*. There is simply no Medicare benefit that covers these services. For these types of denials, beneficiaries may be responsible for the cost of noncovered services even if they did not receive an ABN or any sort of notice informing them of non-coverage before receiving the service. ER-29, ¶ 50.

CMS takes the position in its policy manual that a denial based on a drug being "usually self-administered by the patient" falls into the category of denials that cannot be protected by the statute's liability protection provisions. MBPM Ch. 15 § 50.2.I; ER-29, ¶ 52. CMS states that a denial of Part B coverage for a drug subject to the "self-administered" exclusion is a "'benefit category' denial and not a denial based on medical necessity." *Id.* Treating such a denial as a situation in which Medicare has never covered an item or service, CMS expressly states that a written ABN is "not required" when a beneficiary is to receive a drug that has been determined to be "usually self-administered." *Id.* CMS goes on to state:

> A "benefit category" denial (i.e., a denial based on the fact that there is no benefit category under which the drug may be covered) does not trigger the financial liability protection provisions of Limitation on Liability . . . . Therefore, physicians or providers may charge the beneficiary for an excluded drug.

Id.; ER-29–30, ¶ 53.

As illustrated by the situations of the Plaintiffs described below, the Secretary maintains that no advance notice of non-coverage is required even when a drug that Part B *previously covered* for a beneficiary is added to the SAD List and is therefore abruptly excluded from Part B coverage for that individual. The Secretary's policy is that beneficiaries are not entitled to any forewarning of non-coverage by Part B or potential coverage by Part D. His policy is that beneficiaries are responsible for the full cost of the drug, regardless of their prior coverage for

the drug and their lack of notice about the change in Medicare's coverage terms. ER-30, ¶ 54.

B. Plaintiffs' Situations

Plaintiffs are Medicare beneficiaries who have an ongoing need for Stelara to manage conditions that otherwise cause them debilitating symptoms. ER-18–19, ¶ 2. Beitzel and Goldstein have Crohn's disease and have taken Stelara since the late 2010s every two months to treat severe gastrointestinal pain and inflammation. ER-31, ¶ 60; ER-40, ¶ 105. Beitzel lives alone and also has diagnoses of Parkinson's disease and non-Hodgkin's lymphoma. His progressive Parkinson's symptoms render Beitzel unable to self-inject Stelara. ER-31, ¶ 61. Kraig has severe psoriasis and a rare, destructive type of psoriatic arthritis called arthritis mutilans with "pencil in cup" deformity. ER-37, ¶ 89. Since 2016 she has required Stelara every three months to manage these conditions and alleviate associated symptoms and extreme pain. ER-37, ¶ 90. The medical necessity of Stelara is not in dispute for any of the Plaintiffs.

For years after Plaintiffs were prescribed Stelara, Medicare Part B covered it as a drug furnished "incident to" a practitioner's service in outpatient clinical settings. ER-19, ¶ 2. However, unbeknown to the Plaintiffs, the MACs with jurisdiction over their claims designated Stelara a "usually self-administered" drug that was excluded from Part B coverage, effective October 15, 2021. ER-31–32,

¶ 63; ER-37, ¶ 91; ER-40, ¶ 106. Plaintiffs were not informed of this drastic shift in their established Medicare drug coverage. ER-32, ¶¶ 64, 66; ER-38, ¶ 92; ER-40, ¶ 107. Without notice of this change, Plaintiffs continued to receive their scheduled Stelara injections administered by health care professionals in late 2021 and early 2022. *Id.* (Beitzel received four injections; Kraig got two injections; Goldstein was given two injections). Months later, Plaintiffs finally learned through the quarterly MSNs they received by mail that Part B did not cover the drug. Even worse, the MSNs stated without explanation that they were responsible for the full cost of each non-covered dose of Stelara. ER-32, ¶¶ 65, 67; ER-38, ¶ 93; ER-41, ¶ 108. The prices ranged from approximately $18,000 to $58,000 per dose, resulting in enormous financial liability and distress. *Id.*

As a result of these denials without notice of the coverage change, Plaintiffs experienced serious harm. Kraig was forced to forgo Stelara injections, resulting in painful health setbacks until she could find another source for the drug. ER-40, ¶ 102 (describing her rash that looked like "third degree burn" covering 50% of her body). She also paid a discounted lump sum of $5,000 to her provider after receiving MSNs saying she could be billed around $58,000 for each of her two injections for which coverage was denied. ER-38, ¶ 93; ER-39, ¶ 100. Goldstein received bills and demands for payments for over $30,000 from her provider and from a debt collection agency. Collection efforts were only suspended because her

administrative appeal to Medicare remains pending. ER-41, ¶112; ER-42, ¶ 113; ER-43, ¶ 122.

Plaintiffs found themselves in the alarming situation of having to quickly secure alternate arrangements after the shock of learning that Medicare was not covering their Stelara injections in the same way that it had for years. Beitzel, unable to self-administer, had to urgently find an alternative and eventually recruited a friend who is a retired podiatrist to inject the drug for him. ER-33, ¶ 71; ER-37, ¶ 87. Upon receiving her MSN showing non-coverage of Stelara and asking her provider about it, Goldstein learned that her provider cancelled her next injection, scheduled for just a few days later. ER-41, ¶¶ 108–10. Kraig has had to rely on a charitable program to obtain Stelara, but she does not know how long that assistance will last. ER-40, ¶ 102.

Each Plaintiff also remains financially responsible for at least one injection received without notice of non-coverage. Goldstein remains liable for $18,000 for one injection pending on appeal (ER-41, ¶ 108; ER-43 ¶ 118); Kraig is liable for approximately $58,000 for each of her two injections pending on appeal (ER-38, ¶ 93; ER-39, ¶ 99); Beitzel is liable for at least $43,000 for his fully exhausted December 2021 injection (ER-35, ¶ 81). Of the non-covered injections Plaintiffs received, all claim denials have been upheld in the administrative appeal process other than three that yielded anomalous results. *E.g.*, ER-36, ¶ 83 (Beitzel); ER-42,

¶ 114 (Goldstein). In addressing Plaintiffs' argument that beneficiaries in their situation should not be held liable unless they received advance notice of non-coverage, Administrative Law Judges (ALJs) either concluded that Medicare policy dictated otherwise, or they were reversed. ER-38–39, ¶¶ 97–98; ER-35, ¶¶ 77–80; ER-42, ¶ 116.

C. Procedural History

On September 8, 2023, Beitzel and Kraig filed this putative class action for declaratory and injunctive relief against the Secretary in his official capacity. ER-59. Goldstein joined as a third named Plaintiff in the First Amended Complaint, filed December 26, 2023. ER-60. Plaintiffs alleged that the Secretary's policy of failing to require that adequate notice of the change in Medicare coverage be provided to beneficiaries who had previously received Part B coverage of a drug that has been added to the SAD List, and of failing to waive beneficiaries' liability for any such drugs they receive prior to receiving adequate notice, violates rights guaranteed by the Fifth Amendment Due Process Clause and the Medicare Act. ER-19, ER-49.[4] They sought a declaration that these policies are unlawful and an injunction ordering the Secretary to ensure timely, adequate notice is provided in this situation, and to apply liability protections to beneficiaries who had previously

[4] Plaintiffs additionally alleged that the Secretary's policies subjected Beitzel and a sub-class to disability discrimination in violation of Section 504 of the Rehabilitation Act. ER-50. They do not pursue that claim on appeal.

received Part B coverage of the drug until they receive such notice. ER-50–51. Plaintiffs filed a motion for class certification on January 30, 2024, on which the parties agreed to stay briefing until the motion to dismiss was resolved. ER-79.

The Secretary filed a motion to dismiss pursuant to Rules 12(b)(1), 12(b)(3), and 12(b)(6) on January 31, 2024. ER-60. After oral argument on April 15, 2024, the district judge signed a decision granting the Secretary's motion on April 19, 2024. ER-61, ER-17. The district court held that it lacked subject matter jurisdiction under 42 U.S.C. § 405(g) over all claims other than those stemming from one of Beitzel's Medicare appeals, reasoning that Plaintiffs had not otherwise exhausted their individual administrative remedies, and waiver of exhaustion did not apply because the claims were not "collateral" to a claim for Medicare benefits. ER-9–10. Analyzing the case based solely on Beitzel's fully-exhausted Medicare appeal, the district court further held that Beitzel lacks Article III standing "to the extent that he requests prospective remedies related to drugs other than Stelara." ER-12. It purported to consider his legal claims only to the extent that they seek relief for "past injuries." ER-13. The court then concluded that Beitzel had failed to state claims for which relief could be granted under the Due Process Clause and the Medicare Act. ER-13–16. Plaintiffs filed a notice of appeal on June 3, 2024. ER-61.

SUMMARY OF THE ARGUMENT

1. The district court had subject matter jurisdiction under 42 U.S.C. § 405(g), not only over Beitzel's fully exhausted Medicare claim, but also over Plaintiffs' remaining, non-exhausted claims. Plaintiffs' legal challenges "arise under" the Medicare Act, and their administrative claims met the non-waivable requirement of presentment to the Secretary. The district court erred in concluding that their claims did not qualify for waiver of exhaustion of administrative remedies because they were not "collateral" to a claim for benefits. Plaintiffs challenge systemwide policies requiring the district court to determine what process is required when a drug is added to the SAD List, not to make determinations about entitlement to benefits. Plaintiffs' challenges are collateral, and they satisfy the other requirements for waiver of exhaustion: irreparable harm and futility. Their injuries cannot be fully recompensed by forcing them to complete the administrative process, which also cannot award them the systemic procedural relief they seek.

2. Plaintiffs have Article III standing for the prospective relief they seek. They plausibly alleged ongoing financial injuries that will be redressed by enjoining the Secretary from holding beneficiaries liable for drugs added to the SAD List unless and until they are provided with adequate notice. With continuing redressable injuries, Plaintiffs need not demonstrate that they are likely to suffer

the same injury again in the future. Even so, Plaintiffs have also sufficiently alleged a future injury for purposes of satisfying the relaxed standard for standing to vindicate procedural rights. Their interests remain threatened by the Secretary's policies.

3. The district court concluded that Plaintiffs had not stated a due process claim because the "addition of Stelara to the SAD List" was a decision of general applicability. This analysis wrongly assumed that due process cannot apply when more than a few people are affected by a government decision, and it failed to consider the public benefits context of the case. This Circuit has held that when the government changes eligibility terms for benefits in which individuals have a continuing protected interest, procedural safeguards must apply. In light of that case law and beneficiaries' continuing protected interest in Medicare prescription drug coverage, Plaintiffs alleged a valid claim that they were deprived of a protected interest without adequate notice.

4. Plaintiffs also plausibly alleged that the Secretary violates the Medicare Act by failing to apply its liability protections when a beneficiary receives a previously-covered Part B drug without notice that it has been added to a SAD List. Plaintiffs challenge the Secretary's interpretation that these denials are exempt from liability protection because there is "no benefit" under which the drug can be covered, when coverage is in fact available under Part D. They point to the

agency's own instructions for determining when a drug is self-administered to demonstrate that it is at least plausible that Medicare contractors evaluate whether it is "reasonable and necessary" for a drug to be administered in a clinical setting, thus making the statutory protections applicable. The district court erred by summarily rejecting Plaintiffs' allegations without drawing reasonable inferences in their favor.

STANDARD OF REVIEW

This Court reviews dismissals under Rules 12(b)(1) and 12(b)(6) *de novo*. *Rhoades v. Avon Products, Inc*., 504 F.3d 1151, 1156 (9th Cir. 2007). In assessing a Rule 12(b)(1) dismissal for lack of subject matter jurisdiction based on the face of the complaint, the Court accepts the plaintiff's factual allegations as true and draws all reasonable inferences in the plaintiff's favor. *Leite v. Crane Co*., 749 F.3d 1117, 1121 (9th Cir. 2014). Similarly, in reviewing a dismissal for failure to state a claim under Rule 12(b)(6), the Court takes all factual allegations in the complaint as true and "construe[s] the pleadings in the light most favorable to the nonmoving party." *Knievel v. ESPN*, 393 F.3d 1068, 1072 (9th Cir. 2005).

ARGUMENT

I. PLAINTIFFS ADEQUATELY ALLEGED § 405(g) JURISDICTION BECAUSE THEIR CLAIMS WERE PRESENTED TO THE SECRETARY AND QUALIFIED FOR WAIVER OF EXHAUSTION.

The district court correctly held that it has subject matter jurisdiction under 42 U.S.C. § 405(g) to review Beitzel's legal challenges based on the Medicare claim for his December 2021 injection, for which he fully exhausted administrative remedies. ER-8–9. It erred, however, in determining that it lacks jurisdiction over the remaining claims that Plaintiffs have not exhausted.[5] *Id.* Proper application of § 405(g) and waiver of exhaustion dictates that the court has jurisdiction based on Plaintiffs' non-exhausted claims.

A. The § 405(g) Framework

Borrowing from the Social Security Act, Medicare incorporates judicial review under 42 U.S.C. § 405(g). *See* 42 U.S.C. § 1395ff(b)(1). Individuals may seek review "after any final decision." *Id.* § 405(g). The Supreme Court has long held that the "final decision" requirement consists of two components, only one of which is jurisdictional. The first is "a nonwaivable requirement that a 'claim for benefits shall have been presented to the Secretary.'" *Heckler v. Ringer*, 466 U.S. 602, 617 (1984) (quoting *Mathews v. Eldridge,* 424 U.S. 319, 328 (1976)). The

[5] Beitzel's remaining claims need not be separately analyzed. Yet the district court has jurisdiction over those claims for the same reasons it has jurisdiction over Kraig's and Goldstein's non-exhausted claims.

second is "a waivable requirement that the administrative remedies prescribed by the Secretary be pursued fully by the claimant." *Id.; see also Kaiser v. Blue Cross of Cal.,* 347 F.3d 1107, 1115 (9th Cir. 2003) (exhaustion of administrative remedies is waivable, presentment is not).

Medicare also has a broad administrative channeling requirement, barring federal question jurisdiction over actions to recover on any claim "arising under" the Medicare Act. 42 U.S.C. § 405(h). Thus, Medicare claims are typically directed first to the agency, and § 405(g) provides the jurisdictional basis for judicial review, with limited exceptions. *See Shalala v. Illinois Council on Long Term Care, Inc.,* 529 U.S. 1, 19 (2000).

The Ninth Circuit uses a three-step analysis to determine whether a court has subject matter jurisdiction to hear claims involving Medicare. *Sensory Neurostimulation, Inc. v. Azar,* 977 F.3d 969, 976 (9th Cir. 2020). In Step One, the court decides if the claim "arises under" the Medicare Act, triggering the channeling requirements of § 405(g). If the claim arises under Medicare, the court in Step Two considers whether the plaintiff has satisfied the channeling requirements by presenting the claim and either exhausting administrative remedies or satisfying the criteria for judicial waiver of the exhaustion requirement. If so, the plaintiff may proceed in court under § 405(g) jurisdiction. If the plaintiff has not done so, then in Step Three the court decides if requiring

channeling would mean that there would be "no review at all," in which case federal question jurisdiction may be invoked. *Id.*

In this case, Plaintiffs' claims arise under Medicare, they have satisfied presentment, and Kraig and Goldstein's claims qualify for waiver of exhaustion.

B. Plaintiffs' Claims "Arise Under" Medicare (Step One).

With respect to Step One, there was agreement in the district court that Plaintiffs' claims arise under the Medicare Act. ER-9. The Supreme Court has identified two circumstances in which claims "arise under" Medicare: "(1) where the 'standing and the substantive basis for the presentation of the claims' is the Medicare Act; and (2) where the claims are 'inextricably intertwined' with a claim for Medicare benefits." *Do Sung Uhm v. Humana*, 620 F.3d 1134, 1141 (9th Cir. 2010) (quoting *Ringer*, 466 U.S. at 614, 615) (citations omitted). Here, the Medicare Act provides the standing and substantive basis for the presentation of Plaintiffs' challenges to the Secretary's policies. As will be explained below, their policy challenges are not "inextricably intertwined" with ordinary claims for Medicare benefits in a manner requiring resolution by the agency as opposed to the court. In fact, their challenges cannot be resolved by the administrative process. *See infra* pp. 24–27.

C. Plaintiffs Satisfied Presentment (Step Two).

While the district court did not address the issue, Plaintiffs met the

nonwaivable presentment requirement by presenting their claims to the Secretary before proceeding to court. *See Global Rescue Jets, LLC, v. Kaiser Found. Health Plan, Inc.,* 30 F.4th 905, 912-13, 915 (9th Cir. 2022). After receiving MSNs that, without explanation, denied payment for injections that had previously always been covered, Plaintiffs and/or their providers initiated appeals to the first level of administrative review. ER-32–33, ¶¶ 68–69; ER-38, ¶ 94; ER-41, ¶ 111. They next received decisions tersely citing the SAD policy as the reason for denial. ER-33, ¶ 70; ER-38, ¶ 94, ER-41, ¶ 111. Facing the alarming reality of their financial liability for the injections, they continued their administrative appeals with assistance from a law school clinic and attorneys. ER-33, ¶ 72; ER-38, ¶ 95, ER-41, ¶ 111. They challenged the agency's failure to provide advance notice about the coverage change and to apply liability protections, and the Secretary issued them decisions rejecting those very claims. ER-35–36, ¶¶ 79–80; ER-38–39, ¶¶ 97–98; ER-42, ¶ 116. Plaintiffs have thus brought their legal claims before the Secretary as required by § 405(g).

D. Plaintiffs' Claims Qualify for Waiver of Exhaustion (Step Two).

Waiver of exhaustion is warranted where a claim is "(1) collateral to a substantive claim of entitlement (collaterality); (2) colorable in its showing that denial of relief will cause irreparable harm (irreparability); and (3) one whose resolution would not serve the purposes of exhaustion (futility)." *Johnson v.*

Shalala, 2 F.3d 918, 921 (9th Cir. 1993) (citing *Briggs v. Sullivan,* 886 F.2d 1132, 1139 (1989)).

1. Plaintiffs' Legal Claims Are Collateral to Any Claim for Entitlement to Benefits.

A claim is collateral when it is "not essentially a claim for benefits" and thus not so closely bound up with the underlying merits of entitlement as to "interfere[] with agency process." *Id.* at 921-22 (citing *Bowen v. City of N.Y.*, 476 U.S. 467, 483 (1986) and quoting *Weinberger v. Salfi*, 422 U.S. 749, 765 (1975)). In other words, collaterality exists when plaintiffs are not asking the court to award them benefits or coverage, or to determine the merits of their underlying claims, but instead are challenging the validity of the agency's policies or procedures used in making coverage decisions. Thus, courts have frequently found procedural due process and procedural statutory challenges to be collateral. *See, e.g., Eldridge,* 424 U.S. at 330-31 (policy of terminating disability benefits prior to hearing), *Johnson,* 2 F.3d at 921 (policy of treating in-kind loans as income); *Briggs*, 886 F.2d at 1139-40 (policy of withholding payments from beneficiaries who lacked a representative payee); *Erringer v. Thompson*, 189 F. Supp. 2d 984, 993-94 (D. Ariz. 2001) (policy of denying Medicare payment based on local coverage determinations). Claims are collateral when they seek relief that is unavailable through administrative processes. *Compare Eldridge,* 424 U.S. at 330-31

(procedural claim was collateral), *with Ringer*, 466 U.S. at 614 (denied medical claims of the kind that are typically decided by the agency were not collateral).

Here, Plaintiffs' due process and statutory claims challenge systemwide policies governing procedural protections: notice and waiver of liability. They do not ask the district court to adjudicate the merits of their individual, underlying Part B coverage denials. Their legal challenges only require the court to determine what process is required under the Constitution and federal law when a drug is added to the SAD List. Because Plaintiffs do not seek determinations that their ineligibility for Part B coverage was wrongful, but ask that the Secretary be ordered to provide adequate notice and to cease his policy of holding beneficiaries liable *without* adequate notice, their claims are collateral. *See, e.g., Briggs*, 886 F.2d at 1139-40 (where claimants had already been determined eligible for benefits, decisions to require a representative payee and to suspend payments for lack of a payee, were collateral to their "substantive eligibility for benefits.").

2. The District Court Misunderstood the Exhaustion Inquiry and Applied the Wrong Collaterality Test.

In a brisk analysis with several flaws, the district court held that Plaintiffs' claims were not collateral.

First, the court claimed that Plaintiffs asked it to resolve their "individual claims for benefits." ER-10 (internal quotations omitted). But the decision's only quote from the Amended Complaint in support of this assertion omits critical

language that demonstrates the procedural nature of Plaintiffs' claims and requested remedy. They seek an injunction ordering the Secretary (1) to ensure adequate notice is provided when a Part B drug is added to the SAD List, and (2) to waive liability for beneficiaries who previously received coverage of the drug (*i.e.*, Plaintiffs and class members), "for Part B medications they received or receive . . . after the drug was added to the SAD List but *before they received adequate notice of the change in coverage terms*." ER-51 (emphasis added). In other words, the Secretary would be enjoined from continuing his current notice and liability policies, and could not hold beneficiaries liable *unless and until they have received adequate notice*. This procedural remedy would not require the district court to review Plaintiffs' individual claims, or determine that their denials were wrongful, thus distinguishing it from *Ringer*. It would require the court to analyze whether the Secretary's current policies are lawful under the Constitution and statute, something that cannot be accomplished through the agency's administrative process.

Second, the district court also seemed to assume that if Plaintiffs' success on the merits of their litigation results in the outcome they sought in their administrative appeals, their claims cannot be collateral. ER-10. But that analysis is not consistent with cases like *Eldridge* and its progeny, in which the plaintiff's success would have resulted in reinstatement of benefits until he received the

process due. 424 U.S. at 320; *see also, e.g., Briggs*, 886 F.2d at 1146. Here, Plaintiffs and any similarly situated beneficiary would not be permanently protected from liability even if they succeed in this litigation. To the contrary, as soon as beneficiaries have adequate notice of the non-coverage of their drug by Part B, they would be liable if they continue to receive it "incident to" a physician's service. What is relevant for the collaterality inquiry is the type of challenge brought and whether the analysis the district court must perform intrudes in the agency's traditional domain of benefit entitlement. *Johnson*, 2 F.3d at 922. The district court did not identify even one way that Plaintiffs' claims are so intertwined with benefit determinations that waiving exhaustion until adequate notice is received would constitute "premature interference with agency processes." *Salfi*, 422 U.S. at 765.

Third, the district court misapplied the threshold "arising under" inquiry in Step One of the *Sensory Neurostimulation* analysis to conclude that collaterality was not met in Step Two. Recall that the question of whether a claim is "inextricably intertwined with a claim for benefits" is one of two tests to determine if the claim "arises under" Medicare to require channeling through § 405(g) at all. *See supra* p. 22. The district court did not apply this analysis in Step One, but instead erroneously invoked it as a standard in Step Two to decide that Plaintiffs' claims were not collateral, and so not suitable for waiver of exhaustion of

administrative remedies. ER-10. The two opinions that the court cites for support contradict its position. *See Kaiser*, 347 F.3d at 1112; *Johnson,* 2 F.3d at 921-22. *Kaiser's* footnote four, cited by the district court, does not address collaterality, but the third prong of futility. 347 F.3d at 1115 n.4. The case reinforces that *Ringer's* "inextricably intertwined" test is a *threshold* ("arising under") inquiry, addressing whether claims must be channeled. *Id*. at 1112.

3. Plaintiffs Will Be Irreparably Harmed If Exhaustion Is Not Waived.

The last two elements for waiver of exhaustion, neither of which was addressed by the district court, are also satisfied. Plaintiffs raise "at least a colorable claim" that being forced to exhaust will cause them irreparable harm. *Eldridge,* 424 U.S. at 331. A "'colorable showing' of irreparable harm is one that is not 'wholly insubstantial, immaterial, or frivolous.'" *Briggs,* 886 F.2d at 1140 (quoting *Cassim v. Bowen,* 824 F.2d 791, 795 (9th Cir. 1987)). Plaintiffs state such colorable claims when, because of their physical or other conditions, they would be harmed "in a way not recompensable through retroactive payments." *Eldridge,* 424 U.S. at 331. This Court has held that "economic hardship does constitute irreparable harm," *Johnson,* 2 F.3d at 922 (citing *Briggs*), and that "[b]ack payments . . . . cannot erase either the experience or the entire effect" of time spent without necessities. *Briggs,* 886 F.2d at 1140; *see also Erringer,* 189 F. Supp. 2d at 992. Analyzing irreparability in similar circumstances, the Supreme Court made

the significant observation that "[w]e should be especially sensitive to this kind of harm where the government seeks to require claimants to exhaust administrative remedies merely to enable them to receive the procedure they should have been afforded in the first place." *City of N.Y.,* 476 U.S. at 484.

The above principles are particularly applicable to Kraig's plight. When Medicare terminated Part B coverage of her Stelara injections without notice, she had to stop taking the medication until she could find an affordable way to obtain the drug. ER-40, ¶ 102. As a result, she experienced terrible symptoms from her underlying conditions, including pain and a serious rash that looked like "a third degree burn," and tormented her with itching. *Id*. She eventually enrolled in the drug manufacturer's patient assistance program to obtain Stelara at no cost, but she does not know how long that assistance will last and if she will have to find another source for her medication. *Id*. Absent a judicial remedy enjoining the Secretary's procedural policies, she cannot successfully seek recovery of the thousands of dollars she had to pay her provider, which in turn would mitigate the financial burden of affording her medication going forward. ER-39–40, ¶¶ 97–103. Nor can she favorably resolve the still-pending liability she faces. *Id.* Requiring her to exhaust only to receive procedure she should have been afforded would be unduly burdensome.

Plaintiffs have already waited several months to over a year for decisions on their claims currently sitting in the appeals system. ER-39, ¶ 99; 43, ¶ 118. Kraig and Goldstein allege ongoing distress and anxiety about the financial liability they face. ER-39, ¶ 100; ER-43, ¶ 122. The ALJ who presided at Kraig's hearing made a factual finding that she faces a "difficult financial situation" and "mental stress." ER-39, ¶ 98. After being billed by her provider for over $30,000, Goldstein received letters from a collection agency, and she fears that she will face debt collection efforts again once she has exhausted her pending appeal to Medicare. ER-41–43, ¶¶ 112–113, 122. These harms are not wholly "recompensable" as contemplated by *Eldridge*, and they are far from insubstantial, immaterial, or frivolous. *See, e.g., Davis v. Astrue,* 513 F. Supp. 2d 1137, 1146 (N.D. Cal. 2007) (irreparable harm found where retroactive disability payments could not erase the experience or entire effect of stress, anxiety, and psychiatric symptoms resulting from agency policy). Plaintiffs have made a colorable showing of irreparable harm.

4. Exhaustion of Plaintiffs' Claims Would Prove Futile.

"The Supreme Court has held that the 'ultimate decision of whether to waive exhaustion should not be made solely by mechanical application of the *Eldridge* factors [collaterality and irreparable harm], but should also be guided by the policies underlying the exhaustion requirement.'" *Johnson,* 2 F.3d at 922 (alteration in original) (quoting *City of N.Y.,* 476 U.S. at 484). Thus, futility – the

third factor to be balanced – entails the "intensely practical" consideration of whether, in a given case, the purposes of exhaustion would not be served by requiring the exhaustion of administrative remedies. *City of N.Y.,* 476 U.S. at 484 (quoting *Eldridge,* 424 U.S. at 331, n.11).

Exhaustion has been deemed futile in challenges to systemwide policies because "when the agency applies a 'systemwide policy' that is 'inconsistent in critically important ways with established [law],' nothing is gained 'from permitting the compilation of a detailed factual record, or from agency expertise.'" *Johnson,* 2 F.3d at 922 (quoting *City of N.Y.,* 476 U.S. at 485). In *Briggs,* for example, this Court found it "difficult to see . . . what sort of a detailed record might assist a court in determining the merits of appellants' straightforward statutory and constitutional challenge" to the Secretary's policy of withholding benefits to claimants who lacked representative payees. 886 F.2d at 1140. It also found that the agency had "no particular expertise" to lend to a matter "purely of statutory construction." *Id.* The same holds true in this action. Since no individual facts are contested and Plaintiffs identify no individual errors that need to be corrected, developing a factual record would not aid the court in resolving whether the Secretary's policies violate his due process and statutory obligations. Further, since the agency has no special expertise in construing this principal legal issue, nothing would be gained from requiring exhaustion.

More fundamentally, exhaustion is deemed to be futile when it is "unlikely that an individual claimant could have succeeded in having the Secretary's policy overturned . . . through the administrative process." *Johnson,* 2 F.3d at 922-23 ("[r]equiring each individual to exhaust his administrative remedies would result in a considerable waste of judicial resources."). Particularly where the policy in question "is a directive of the Secretary himself . . . . it is reasonable to operate on the assumption that the lower levels of the administrative review process will not rule in favor of any individual claimant." *Briggs,* 886 F.2d at 1141.

Here, Plaintiffs dispute official policies that they cannot overturn through the administrative process. At Kraig's hearing, the ALJ indicated her intention to waive liability because she "logically assumed that a Provider needed to advise the Beneficiary that the injection could not be covered." ER-39, ¶ 98. Nevertheless, she then issued a contrary decision, explaining that she was constrained by "Medicare policy and guidance." *Id.* After Beitzel won a favorable ALJ ruling in one of his appeals, CMS referred the decision to the Appeals Council, the final level of appeal, which reversed on the grounds that the ALJ had failed to abide by the manual's coverage and liability policies. ER-35, ¶¶ 79–80. These experiences show why exhaustion of administrative remedies is futile and should be waived. *See Hart v. Colvin,* No. 15-cv-00623-JST, 2015 WL 4396259, at *7 (N.D. Cal. Jul.

17, 2015) (futility satisfied because "Defendant has already stated the SSA's intention to continue [the challenged policy]").

Although the district court did not expressly address futility in denying waiver of exhaustion, its opinion is reflected in its assertion that Plaintiffs have "found some measure of success" in pursuing their administrative appeals. ER-11, n.3. But this ignores that Plaintiffs challenge centralized polices, and it also mischaracterizes what actually happened. The few favorable administrative decisions Plaintiffs received were either patently inconsistent with Medicare policy (*e.g.*, granted coverage of one of Beitzel's injections because he is unable to self-administer, ER-36, ¶ 83), or anomalous (*e.g.*, found it relevant that Goldstein's injection occurred inside the 45-day period when *providers* were presumed not to know of the coverage change, ER-42, ¶ 114).

It is of no consequence that Plaintiffs obtained other remedies for a few of their denied injections in the administrative process, because the point of this case is to correct the Secretary's policy and practice. *See, e.g., City of N.Y.,* 476 U.S. at 485-86 (finding it irrelevant in the context of procedural challenge that some class members might have obtained benefits if they had exhausted); *Duggan v. Bowen,* 691 F. Supp. 1487, 1505 (D.D.C. 1988) (finding futility where "plaintiffs cannot obtain what they are initially entitled to receive . . . even if they succeed on their appeals" since the challenged policy is "relentlessly final"). Plaintiffs are left with

only administrative decisions rejecting the notice and liability claims they raise in this case. Since straightforward application of the Secretary's challenged policies will result in upheld denials for the claims that are still pending, there is no purpose served by requiring exhaustion.

Since presentment and the factors warranting waiver of exhaustion are met, Plaintiffs satisfy the final decision requirement of § 405(g), and the district court has jurisdiction over the claims of Kraig and Goldstein as well as Beitzel.

II. PLAINTIFFS PLAUSIBLY ALLEGED STANDING FOR ALL OF THE INJUNCTIVE RELIEF THEY SEEK.

To establish Article III standing, a plaintiff must plausibly allege that she has suffered (1) an injury in fact, (2) that is fairly traceable to the challenged conduct, and (3) likely to be redressed by a favorable decision on the merits. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-61 (1992). A plaintiff must demonstrate standing for each form of relief sought, such as, injunctive relief and damages. *DZ Reserve v. Meta Platforms, Inc*., 96 F.4th 1223, 1240 (9th Cir. 2024). At the pleading stage, "general factual allegations of injury resulting from the defendant's conduct may suffice, for on a motion to dismiss" the court presumes that "general allegations embrace those specific facts that are necessary to support the claim." *Maya v. Centex Corp*., 658 F.3d 1060, 1068 (9th Cir. 2011) (quoting *Lujan*, 504 U.S. at 561). A court need only find one plaintiff who has standing to satisfy Article III's

case-or-controversy requirement. *Rumsfeld v. Forum for Acad. & Inst. Rights, Inc.*, 547 U.S. 47, 52 n.2 (2006).

In this case, there was no dispute over the traceability or redressability elements of standing, nor did the Secretary or district court question that Plaintiffs each have sustained injuries in fact. But the district court focused on Plaintiffs' requested injunctive relief and concluded that Beitzel lacks a "threatened injury [that] must be certainly impending." ER-12 (quoting *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013)). It thus purported to analyze the merits of the case based on Beitzel's standing to remedy "past injuries" stemming only from Stelara's addition to the SAD List, but not to seek relief "for any prospective injuries that might be caused by other drugs being listed in the future." ER-8; ER-12–13. This analysis was incorrect.

First, the district court misconstrued the purpose of this case and nature of the relief sought. As noted above, Plaintiffs[6] challenge the Secretary's nationwide policy of failing to require constitutionally adequate notice, and failing to apply the statute's liability protections. They neither seek damages nor ask the district court to adjudicate their entitlement to Medicare coverage. The district court's footnote that neither party disputes that Beitzel has standing to seek relief "for Stelara

[6] The district court analyzed standing with regard to Beitzel alone. Because Plaintiffs contend that the district court had jurisdiction to hear Kraig's and Goldstein's claims as well, they refer to "Plaintiffs" rather than only to "Beitzel."

injections that were denied coverage" misses the essence of the case. ER-12, n.5. Beitzel and the other Plaintiffs seek only an injunction ordering the Secretary to modify his policies in order to provide notice and protect beneficiaries against liability.

Second, for prospective injunctive relief, plaintiffs must allege "*either* 'continuing, present adverse effects' due to . . . [defendant's] past illegal conduct . . . *or*, 'a sufficient likelihood that [they] will again be wronged in a similar way." *Villa v. Maricopa Cty.*, 865 F.3d 1224, 1229 (9th Cir. 2017) (quoting *O'Shea v. Littleton*, 414 U.S. 488, 495-96 (1974) and *City of L.A. v. Lyons*, 461 U.S. 95, 111 (1983) (citation omitted) (emphasis added)). Plaintiffs satisfy both criteria, particularly because they allege violation of procedural rights.

Continuing Injury

Plaintiffs carry ongoing financial liability traceable to the Secretary's notice and liability policies that would be remedied via the injunctive relief they seek. *Haro v. Sebelius* demonstrates the correct analysis for standing based on a present, continuing injury. 747 F.3d 1099 (9th Cir. 2013), *as amended* (Jan. 2, 2014). Haro, like the Plaintiffs here, challenged a policy of the Secretary. In her case, the policy involved Medicare acting as a "secondary" insurer, such as when a beneficiary is injured in an accident and another insurer has primary responsibility. *Id.* at 1105. Having been injured in a car accident, Haro brought a class action claiming that the

Secretary violated due process and the Medicare Act when the agency sent demand letters seeking upfront reimbursement from beneficiaries who had received payment from a primary insurer while they were still appealing or requesting waiver of their Medicare reimbursement obligations. *Id.* at 1104, 1105-06. The district court enjoined the Secretary from demanding such upfront payment from beneficiaries, and from demanding that their attorneys withhold settlement proceedings until Medicare was reimbursed. *Id.* at 1107 (Haro's attorney also brought an individual claim).

This Court noted that Haro's injury was ongoing at the time the complaint was filed because she was "deprived of $103.87," and that an injunction prohibiting the Secretary from withholding reimbursement payments until the appeals process was complete "would have redressed Haro's injury." *Id.* at 1109; *see also id.* (same for her attorney who was "subject[] . . . to individual liability"). Thus, the argument that Haro was "not likely to suffer the same injury again and . . . therefore [could not] show that injunctive relief would redress her injury" carried no weight. *Id.* at 1108. Haro's ongoing injury would have been redressed by "a properly framed injunction." *Id.* at 1109. Plaintiffs in this case also have ongoing financial injuries. As in *Haro*, an injunction prohibiting the Secretary from holding beneficiaries liable for drugs added to the SAD List unless and until they are provided with adequate notice would remedy their injuries, and that is the

remedy Plaintiffs request. ER-51. As in *Haro*, Plaintiffs need not demonstrate that they are likely to suffer the same injury in the future because they have actual, ongoing injuries that are redressable with "a properly framed injunction." *Haro,* 747 F.3d at 1108-09.

The Court understood that Haro's injuries would have been redressed by the relief she sought, enjoining the Secretary's withholding policy. This required amending the demand letters that would be sent to beneficiaries, refraining from withholding money in the future, and returning money already withheld. While the district court did not fully explain the relief it was contemplating in this case, if it meant that Beitzel only had standing to seek resolution of his liability for Stelara and no other relief, that would be equivalent to holding that Haro could have requested resolution of her liability from her one accident and nothing else – no prospective amending of demand letters or change in withholding policy. But that would not make sense, and that is not what this Court held. Plaintiffs here have standing to modify the Secretary's procedural policies that caused their ongoing injuries, just as Haro did.

Procedural Injury

Even if Plaintiffs must also plausibly allege a future injury to demonstrate standing for the injunctive relief they seek, they have done so here. "When a plaintiff alleges a procedural violation of her rights, she is excused from the

'normal standards for redressability and immediacy.'" *Wright v. Serv. Emps. Int'l Union Local 503*, 48 F.4th 1112, 1120-21 (9th Cir. 2022) (quoting *Cantrell v. City of Long Beach*, 241 F.3d 674, 682 (9th Cir. 2001). To establish procedural standing, a plaintiff need only show "that [she] was accorded a procedural right to protect [her] interests and that [she] has concrete interests that are threatened." *Id.* (quoting *City of Las Vegas v. FAA*, 570 F.3d 1109, 1114 (9th Cir. 2009)) (alterations in original); *see also Ochoa v. Pub. Consulting Grp., Inc.*, 48 F.4th 1102, 1107 (9th Cir. 2022) (discussing "less demanding standard" to assert procedural rights because "procedural rights are special") (citing *Lujan*, 504 U.S. at 572 n.7).

In *Ochoa*, the plaintiff had a Fourteenth Amendment due process right that protected her concrete liberty interest in avoiding compelled speech caused by unauthorized withholding of union dues. 48 F.4th at 1107. While the court described her future harms as "speculative" because it was unknown whether she would ever again experience an unauthorized withholding, as an employee she remained "at risk" of erroneous withholdings. *Id.* That "risk of future injury" was "'sufficiently real' to meet the low threshold required to establish procedural standing." *Id.* (quoting *Yesler Terrace Cmty. Council v. Cisneros*, 37 F.3d 442, 446 (9th Cir. 1994)).

Plaintiffs here have a procedural right to due process under the Fifth Amendment that protects their concrete interest in receiving the Medicare coverage to which they are entitled. ER-48, ¶ 138; *Grijalva v. Shalala*, 152 F.3d 1115, 1121 (9th Cir. 1998), *vacated on other grounds*, 526 U.S. 1096 (1999); *Barrows v. Becerra*, 24 F.4th 116, 140-41 (2d Cir. 2022); *see also infra* pp. 43–44 (discussing "legitimate claim of entitlement" to Medicare prescription drug coverage). They also have a statutory right to advance notice to protect their concrete interest in avoiding financial liability. ER-27–28, ¶¶ 43–47; *see also supra*, pp. 9–10.

Thus, in addition to Plaintiffs' ongoing injuries, they have concrete interests that remain threatened by the Secretary's challenged policies. They are older adults with chronic medical conditions requiring multiple medications (ER-46, ¶ 132); the Secretary continues to add Part B drugs to the SAD Lists, as described in the Amended Complaint (ER-45–46, ¶¶ 128–32); and the Secretary's express policy requires no notice when a drug's coverage terms change because it is determined to be self-administered. Beitzel, for instance, has non-Hodgkin's lymphoma (ER-31, ¶ 61), and Part B drugs include those typically infused in outpatient settings (ER-24, ¶ 28), such as chemotherapeutic agents. He remains at risk for re-injury by lack of notice regarding other drugs under the Secretary's continuing policies. In general, Plaintiffs' risk of being harmed again by inadequate notice of a change in

coverage terms for a critically-required drug is "sufficiently real" to meet the relaxed standard for procedural standing. *Ochoa*, 48 F.4th at 1107.

Finally, if the Court were to conclude that challenges to the Secretary's notice procedures can only happen after a change in drug coverage has occurred, and the remedy can apply only to the one specific drug about which the Secretary failed to provide notice, then the Secretary's policies regarding notice and liability procedures "would forever escape review," an outcome this Court has rejected. *Citizens for Better Forestry v. U.S. Dep't of Agric.*, 341 F.3d 961, 973-74 (9th Cir. 2003). Plaintiffs have been injured. The Secretary's policies are not changing. Plaintiffs "must, at some point, have standing to challenge" the procedural violations they have alleged. *Id*. at 974.

III. PLAINTIFFS ADEQUATELY STATED CLAIMS FOR RELIEF.

To adequately state a claim, Plaintiffs must allege "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). Because Plaintiffs' constitutional and statutory claims were dismissed for failure to state a claim, "the question below was 'not whether [Plaintiffs] will ultimately prevail' . . . but whether [their] complaint was sufficient to cross the federal court's threshold." *Redd v. Guerrero,* 84 F.4th 874, 892 (9th Cir. 2023) (quoting *Skinner v. Switzer*, 562 U.S. 521, 529-30 (2011)).

A. Plaintiffs Sufficiently Pleaded a Due Process Claim Because They Alleged They Were Deprived of a Protected Interest Without Adequate Notice. The District Court Erroneously Applied the "Legislative Act" Doctrine.

No person may be deprived of "life, liberty, or property without due process of law." U.S. Const., Amend. V. A procedural due process claim hinges on "(1) a protectible liberty or property interest . . . ; and (2) a denial of adequate procedural protections." *Thornton v. City of St. Helens*, 425 F.3d 1158, 1164 (9th Cir. 2005) (citation and internal quotations omitted); *see also Redd*, 84 F.4th at 891. Plaintiffs plausibly alleged both elements.

1. Protected Property Interest

Plaintiffs alleged that Medicare fails to require timely, adequate notice when a drug previously covered by Part B shifts to coverage solely by Part D because CMS determines that it is usually self-administered. ER-49. Notably, while Medicare's classification of a drug as self-administered ends coverage by Part B, it does not *eliminate* Medicare coverage of the drug in question. As CMS concedes, beneficiaries will virtually always be eligible for Part D coverage. ER-26, ¶ 38. The Secretary thus recognizes both that beneficiaries have an ongoing need for their medications, and that they can continue to look to Medicare for coverage after Part B will no longer pay for a drug deemed "usually self-administered." In other words, beneficiaries have a general and continuing interest in Medicare coverage of their prescription drugs. ER-48, ¶ 138.

Plaintiffs thus satisfactorily alleged a protected property interest in continuing Medicare coverage of their prescription medication. Property interests arise in the context of government benefits when the law confers a "legitimate claim of entitlement" to the benefit. *Nozzi v. Hous. Auth. of City of L.A.*, 806 F.3d 1178, 1191 (9th Cir. 2015), *as amended on denial of reh'g and reh'g en banc* (Jan. 29, 2016). Protected entitlements exist when government officials lack discretion to deny a benefit to those who qualify for it. *Ching v. Mayorkas*, 725 F.3d 1149, 1155 (9th Cir. 2013). Medicare coverage has long been a recognized property interest for beneficiaries that triggers procedural protections. In some instances this recognition was implied as courts simply evaluated what process was due, an assessment that was only necessary because there was a property interest protected by the Fifth Amendment. *E.g., Grijalva*, 152 F.3d at 1121 (finding inadequate procedural protections when private Medicare health plans denied coverage of services).[7] In other instances, it was explicit. *E.g., Barrows*, 24 F.4th at 139-43 (finding protected property interest in Medicare coverage of inpatient hospital services).[8]

The Amended Complaint in this case plausibly alleged that Plaintiffs were

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[7] *See also, e.g., Schweiker v. McClure*, 456 U.S. 188, 198 (1982); *Kraemer v. Heckler*, 737 F.2d 214, 221-22 (2d Cir. 1984).

[8] *See also, e.g., Gray Panthers v. Schweiker*, 652 F.2d 146, 148 n.2, 152 n.14 (D.C. Cir. 1980); *Zinman v. Shalala*, 835 F. Supp. 1163, 1168 (N.D. Cal. 1993) (citing *Gray Panthers*, 652 F.2d at 152 n.15, 158, 167-72).

deprived without adequate notice of Medicare prescription drug coverage to which they had a continuing claim of entitlement. Medicare has no discretion to deny prescription drug coverage to those who meet the program's criteria, and this applies just as much to Part D as it does to Part B. *See* 42 U.S.C. § 1395w-101(a)(1) ("each part D eligible individual . . . is *entitled* to obtain qualified prescription drug coverage . . . as follows:") (emphasis added); ER-26, ¶ 38 (coverage of drugs that become excluded under Part B is available under Part D); ER-47, ¶ 136 (steps beneficiaries can take to obtain continuing Medicare drug coverage, including ensuring that they are enrolled in a Part D plan with a formulary that includes their drug, obtaining any required prior authorizations, and pursuing any necessary appeals).

2. Denial of Adequate Notice

"[O]ne of due process's central and undisputed guarantees is that, before the government permanently deprives a person of a property interest, that person will receive—at a minimum—notice." *Wright v. Beck*, 981 F.3d 719, 727 (9th Cir. 2020) (citing *Mullane v. Cent. Hanover Bank & Trust Co.*, 339 U.S. 306, 313 (1950)). As this Court has noted, the Supreme Court has "adhered unwaveringly" to this principle, often holding that "inadequate attempts" and "outright failures" to provide notice violate due process. *Id.* at 728 (quoting *Mennonite Bd. of Missions v. Adams*, 462 U.S. 791, 797 (1983) and collecting cases).

To satisfy due process, "notice must be of such a nature as reasonably to convey the required information." *Mullane*, 339 U.S. at 314. Constitutionally adequate notice regarding changes to a property right "must be 'reasonably calculated, under all the circumstances, to apprise interested parties . . . with due regard for the practicalities and particularities of the case[.]'" *Nozzi*, 806 F.2d at 1194 (quoting *Mullane*, 339 U.S. at 314); *see also id.* (means employed must be "'reasonably certain' to 'actually inform' the party") (quoting *Mullane*, 339 U.S. at 315). "[I]n choosing the means, one must take account of the 'capacities and circumstances' of the parties to whom the notice is addressed." *Id.* (quoting *Goldberg v. Kelly*, 397 U.S. 254, 268-69 (1970)).

Nozzi v. Housing Authority found that a flyer purporting to inform residents of change in the calculation of their Section 8 housing benefits was "incomprehensible to anyone without a relatively sophisticated understanding" of the program, and contained no information on how to obtain further assistance. *Id*. It was thus "not reasonably calculated to give notice to the average recipient" of the pertinent change in benefits. *Id*. at 1194-95. *Nozzi* also found that it would not burden the housing authority to issue a flyer that met due process requirements by providing an "elementary explanation" of the benefits change and its effect on tenants' rights. *Id*. at 1197-98.

Plaintiffs in this case plausibly alleged a deprivation of coverage without

sufficient notice. Having received coverage of their drug from Part B for years, they had no reason to believe those coverage rules had changed until they received MSNs showing denied claims well after they received their scheduled injections. *E.g.*, ER-38–39, ¶ 97. It was only through administrative appeals of their denied claims that they learned of the reason for the denials. *E.g.*, ER-33, ¶ 70. And they were still on their own to seek out and piece together information about how to obtain their medically necessary drug without incurring massive costs. *E.g.*, ER-41, ¶¶ 109–10. The information they acquired on their own was too late to prevent or remedy health relapses, financial liability already incurred, or the distress and alarm they experienced. *E.g.*, ER-40, ¶ 102. The Amended Complaint demonstrates how, with adequate notice, Plaintiffs and individuals in their position could take actions to prevent interruptions in treatment and avoid financial liability—in short, how they could ensure continuity of coverage. ER-47, ¶ 136. But under the Secretary's policies and practices, Plaintiffs and those similarly situated have no opportunity to take those actions.

While this Court need not determine the precise requirements of notice guaranteed to Plaintiffs at this stage of the litigation, it is clear that the Secretary's current policies and practices cannot pass muster. Medicare beneficiaries whose drug is added to a SAD List are not "actually informed" of its exclusion from Part B coverage, as the Plaintiffs' experiences demonstrate, and as the Secretary's

written policy confirms. ER-29–30, ¶¶ 52–54; ER-32, ¶ 64; ER-38, ¶ 92; ER-40, ¶ 107. Nor could anything cited by the district court suffice as adequate notice under the standards set forth in *Mullane*. The court claimed there was "appropriate general notice to the public," appearing to refer to the SAD Lists themselves, which, as the Amended Complaint explains, are published on CMS's website as Local Coverage Articles. ER-14. However, the district court ignored the allegation that, by the express terms of the Medicare Benefit Policy Manual, the Lists are published for the benefit of medical *providers*, not for the general public, let alone for the average older or disabled Medicare recipient, who are most grievously harmed when no notice is given. ER-26, ¶ 36.

Any review of the SAD Lists themselves also shows that they are clearly intended for an audience of medical professionals, and not "reasonably calculated to give notice to the average [Medicare beneficiary]" of whether a drug they require can no longer be covered by Medicare Part B. *Nozzi*, 806 F.3d at 1194-95; *see generally* ADD-6–36. Upon following a link to a Local Coverage Article, users are greeted with, *inter alia*, language about "CPT Codes" and obscure sentences such as "Any miscellaneous HCPCS codes (J3490, J3590 and C9399) billed to Medicare for drugs that are listed in the Coding Table Information below will be denied." The excluded drugs themselves are listed under a section titled "Coding Table Information," and to say the text is not written in laymen's terms is an

understatement. *See Nozzi*, 806 F.3d at 1194-95 (flyer was beyond understanding of average recipient). In fact, there is nothing in the Local Coverage Article mentioning "Medicare Part B coverage" or the fact that beneficiaries can seek coverage of excluded drugs under Part D. What is more, as Plaintiffs alleged, beneficiaries have no way to know these SAD Lists even exist, much less the specific "Article Number" to search for, until it is too late. ER-33, ¶ 70; ER-38, ¶ 94.

The district court also mentioned the "years-long advocacy campaign to stop Stelara and other drugs from being added to the SAD Lists." ER-14. But these efforts were pursued by medical *provider* groups. ER-43–46, ¶¶ 123–31. The Amended Complaint lacks any allegation that the advocacy of rheumatological or other medical organizations "actually informed" Plaintiffs of the upcoming addition of Stelara to the SAD List, or its potential effect on their Medicare coverage. Finally, just because the Lists including Stelara "were made public back in 2020 before taking full effect in 2021" does not render their publication constitutionally adequate notice. ER-14. Besides the fact that the Local Coverage Articles did not contain information that was understandable to beneficiaries and did not address pertinent coverage ramifications, information provided in 2020 cannot be sufficient notice for coverage denials taking place a year or more later. *Nozzi* rejected a similar argument. 806 F.3d at 1196-97.

Additionally, Plaintiffs are not disputing the Secretary's underlying determination that their medication is "usually self-administered," nor are they requesting a hearing as part of the remedy in this case. "Procedural safeguards come in many forms, including, *inter alia*, 'timely and adequate notice'" *Id.* at 1192 (quoting *Goldberg*, 397 U.S. at 267). "Which protections are due" varies according to the particular situation and the rights and interests at stake. *Id*. (citing *Eldridge*, 424 U.S. at 334-35; *Mullane*, 339 U.S. at 314). In this situation, what Plaintiffs require to protect their rights is constitutionally adequate notice of non-coverage by Part B of their previously covered drug. Notice would provide the opportunity to arrange for coverage under Part D while avoiding interruptions in treatment and enormous financial liability. ER-47–48, ¶¶ 136–37. Once adequately and timely informed of their options, beneficiaries can seek coverage and use the administrative appeal system already built into Part D, if needed. *See* 42 C.F.R. §§ 423.566–423.604 (appeals under Part D). *See also Nozzi*, 806 F.3d at 1198 (residents sought only a "uniform notice" that explained effect of the change in benefits in a manner sufficient to inform that they might have to plan for decrease in subsidy and accompanying increase in rent).

In short, Plaintiffs' allegations, which must be taken as true and in any event are not contested, state a plausible procedural due process claim. Nothing cited by the district court is "reasonably certain to inform" the average Medicare

beneficiary of the change to their prescription drug coverage when one of their necessary medications is determined to be self-administered. *Mullane*, 339 U.S. at 315. Even the district court recognized the unfairness of expecting "Beitzel, or any Medicare beneficiary generally, to keep abreast of such complex regulatory developments in order to avoid astronomical medical bills." ER-14. Giving "due regard for the practicalities and peculiarities of the case," any burden on the Secretary to require timely notice would be minimal. Medicare has records of which beneficiaries received each particular drug covered under Part B's "incident to" provision, and it already requires issuance of "Advance Beneficiary Notices" in comparable circumstances. *Mullane*, 339 U.S. at 314; ER-28, ¶¶ 46–47. As noted, the Secretary has chosen to furnish advance "Provider Notice of Noncovered Drugs." ER-26, ¶ 36. Plaintiffs should be allowed to continue with their claim that they are entitled to adequate notice as well.

3. Erroneous Application of "Legislative Act" Doctrine

Relying on doctrine regarding "laws of general applicability," the district court concluded that Plaintiffs had not stated a valid due process claim. ER-13. The court stated that the "addition of Stelara to the SAD List" was the relevant "decision of general applicability," and referred to cases in which "general notice as provided by law" was deemed sufficient to inform individuals affected by government actions. ER-13–14 (citing, *e.g.*, cases in which plaintiffs affected by

zoning or other land use policies "received all the process due . . . when . . . elected officials discharged their legislative responsibilities in the manner prescribed by law." *Halverson v. Skagit Cty.*, 42 F.3d 1257, 1260 (9th Cir. 1994), *as amended on denial of reh'g* (Feb. 9, 1995) (internal quotations and citation omitted)). This reasoning was faulty because (1) it wrongly assumed that due process cannot apply when more than a few people are affected by a government decision, and (2) it failed to consider that in the public benefits context, courts focus on whether individuals have an adequate opportunity to qualify for continuing benefits when eligibility rules are modified.

In considering whether due process protections apply to "legislative acts," some courts focus on formalistic distinctions between "legislative" and "adjudicative" or "administrative" decisions. But the Ninth Circuit holds that the "character of the action, rather than its label, determines whether those affected by it are entitled to constitutional due process." *Harris v. Cty. of Riverside*, 904 F.2d 497, 501-02 (9th Cir. 1990) (analyzing principles originating in *Bi-Metallic Inv. Co. v. State Bd. of Equalization*, 239 U.S. 441 (1915)). In this case, the district court erred by treating the mere fact that a government decision affects a large number of people as virtually dispositive of whether due process protections apply. ER-13–14. That may be the general rule in the context of zoning cases such as those cited by the district court. *E.g., Halverson*, 42 F.3d at 1261; *Christensen v.*

Yolo Cty. Bd. of Supervisors, 995 F.2d 161, 166 (9th Cir. 1993) (discussing due process requirements for "[z]oning decisions that affect a large number of people, as opposed to zoning decisions targeted at a small number of individuals"). In the benefits context, however, where almost any rule change necessarily affects more than a few individuals, courts have focused instead on whether those affected have a continuing property interest in the benefit in question and whether they could qualify for the benefit under the modified eligibility rules if given the opportunity. Thus, this Court held that when Congress amends the eligibility terms for health benefits in which individuals have a protected property interest, procedural safeguards must be applied before those benefits are lost. *Greene v. Babbitt*, 64 F.3d 1266, 1273-74 (9th Cir. 1995); *see also Nozzi*, 806 F.3d at 1186 (around 45% of approximately 45,000 Section 8 beneficiaries were affected by the benefit change for which notice was required).

In *Greene*, Congress had amended federal law to make health care coverage and other benefits for Native Americans contingent on federal tribal recognition. 64 F.3d 1269. The Samish Indians then challenged an agency procedure that denied tribal recognition (and thus health benefits) without a hearing or other procedural safeguards. *Id*. After finding that the health benefits constituted a protected property interest, the Court noted that while Congress was "free to change eligibility criteria for federal benefits . . . . once Congress has narrowed

eligibility for fundamental health and welfare benefits by conditioning eligibility on tribal recognition, the due process clause requires a meaningful hearing to determine whether those previously eligible can meet the new and narrowed requirements." *Id*. at 1272-73, 1273. So while the "legislative" action of enacting a generally applicable law did not give rise to a constitutional issue (Congress was not constrained by due process in its decision to change the eligibility criteria for health coverage), the "loss of individual benefits . . . trigger[ed] . . . due process concerns." *Id*. at 1273. Accordingly, the Court found a due process violation and analyzed what procedural safeguards were required. *Id.* at 1274-75.

Relying on *Greene*, *Youakim v. McDonald*, 71 F.3d 1274 (7th Cir. 1995), reinforced the principle that due process protections apply when eligibility rules for benefits are changed, notwithstanding that the action giving rise to the new eligibility terms may be labeled "legislative." The Illinois state legislature had instituted a requirement that all homes providing foster care be licensed before children could be eligible for financial foster care benefits. *Id.* at 1281. Had the legislature's plan not been enjoined, the "significant and potentially devastating" impact of the change would have been abrupt termination of benefits for children who had been placed in homes with relatives—an arrangement that had not previously required licensure—while the relatives attempted to become licensed. *Id*. *Youakim* found the circumstances in *Greene* "virtually indistinguishable"

because there too the government had amended eligibility rules for a benefit, the effect of which was to temporarily eliminate assistance for current recipients while they attempted to satisfy the newly applicable criteria. *Id.* at 1291. "[W]e agree with the Ninth Circuit that the Due Process Clause does not permit the State to withhold benefits without determining whether current recipients can meet the new requirement." *Id.*

The families in *Youakim*, like the Samish Indians in *Greene* and the Plaintiffs in this case, did not challenge the substance of the rule changes adopted by the government. *Id.* at 1290. Illinois was free to restrict foster care benefits; Congress could restrict health benefits for Native Americans; and CMS can restrict Medicare prescription drug coverage pursuant to statute by determining that a drug is usually self-administered. The *Youakim* plaintiffs challenged only "the State's failure to provide them an opportunity to qualify under the new system before their benefits are eliminated." *Id.* The Seventh Circuit recognized that most homes could satisfy the modified requirements for foster care benefits "if given an adequate opportunity." *Id.* at 1291.

Plaintiffs in this case make the same request: timely notice so that they have an adequate opportunity to obtain Medicare drug coverage under the newly applicable criteria *before* experiencing astronomical financial liability or adverse health ramifications from forgoing their medication. As in *Youakim*, the

government action—a determination that a drug is usually self-administered—results in narrowed eligibility requirements (through Part D) that most affected individuals could meet if given the opportunity. ER-26, ¶ 38. But they require advance notice that alerts them of non-coverage by Part B and of the actions that may be required for coverage by Part D. ER-47, ¶ 136; *see also Youakim*, 71 F.3d at 1290 n.14 (distinguishing cases in which there was "no further action an affected individual could take to avoid the impact of the challenged legislation."). In short, the legislative action doctrine poses no bar to Plaintiffs' due process claim.

Separately, to the extent that the district court made unsupported factual assumptions to underpin its conclusion regarding Plaintiffs' due process claim, it should not have done so on a motion to dismiss. The court devoted only one paragraph to the facts in support of its due process holding. In doing so it stated that notice to the public had been "appropriate," and seemed to assume that Beitzel was aware of communications between CMS and medical provider organizations. ER-14. These assertions were unfounded (*see supra* pp. 47–48), and even the inapposite zoning decisions on which the district court relied were decided after summary judgment, giving courts the opportunity to consider evidence regarding the "character of the action" in question. *Halverson*, 42 F.3d at 1258-59; *Christensen*, 995 F.2d at 166; *see also Bols v. Newsom*, 515 F. Supp. 3d 1120,

1129 (S.D. Cal. 2021) (procedural due process claim could not be resolved on motion to dismiss, citing *Halverson*.).

Plaintiffs sufficiently identified a government action to which due process protections apply. They should be allowed to proceed with their claim.

B. Plaintiffs Plausibly Alleged that the Liability Protections of the Medicare Act Should Apply.

The district court summarily dismissed Plaintiffs' claim under the Medicare Act for failure to waive liability for drugs that are added to the SAD List for beneficiaries who did not know of non-coverage. ER-15–16. Drawing all reasonable inferences in favor of the Plaintiffs, however, the Amended Complaint plausibly alleged that the liability protections of the Medicare Act should apply in that situation.

Plaintiffs challenge the Secretary's interpretation of the statute. For purposes of this case, the liability protections are triggered when a denial occurs because an item or service was not "reasonable and necessary." 42 U.S.C. § 1395pp(a)(1) (citing *id*. § 1395y(a)(1)(A)). The Medicare Benefit Policy Manual, which interprets the statutory liability protections as they apply to self-administered drugs, claims that a denial on the grounds that a drug is subject to the self-administered exclusion is not based on the item being "not reasonable and necessary," but a benefit category denial, "i.e., a denial based on the fact that there is *no benefit category under which the drug may be covered*." MBPM Ch. 15

§ 50.2.I; ER-29–30, ¶¶ 52–53 (emphasis added). The Manual thus concludes that the liability protections are not triggered by such a denial, and the statute's second inquiry about whether the beneficiary knew, or could have been expected to know, of non-coverage is never reached. That reasoning is flawed. As discussed above and as CMS stated, when a drug is added to a SAD List, it is excluded from Part B coverage but can almost always be covered by Part D. ER-26, ¶ 38 (citing 88 Fed. Reg. 52387). To say that a denial based on the self-administration exclusion is a "benefit category" denial cannot be a reason the liability protections do not apply because it is simply not correct.

Once that interpretation is eliminated, Plaintiffs' allegations and CMS's own words about the actual basis for denial remain. To be sure, Medicare's *stated* rationale is that the drug has been "deemed self-administered." *E.g.* ER-33, ¶ 70. But in practice, when a MAC determines that a drug is usually self-administered by the patient, it is making a medical necessity determination, and the Secretary should not be able to sidestep liability protections by misclassifying a "reasonable and necessary" denial as a "benefit category" denial.

For instance, CMS instructs MACs that they will be able to make the determination regarding self-administration for certain drugs based on "the nature of the condition(s) for which they are administered or the usual course of treatment for those conditions." MBPM Ch. 15 § 50.2.A (explaining that injections for

migraines are by their nature self-administered; injections for anemia secondary to chemotherapy are not). CMS also provides certain "presumptions" MACs are to use absent reliable statistical data to determine whether a drug is usually self-administered. The presumptions include, for instance, that drugs delivered by intramuscular injection are not usually self-administered, but MACs "may consider the depth and nature of the particular intramuscular injection in applying this presumption." *Id.* § 50.2.C. In other words, some intramuscular injections *may* be deemed self-administered. For subcutaneous injections, MACs are instructed to examine the use of the particular drug and to consider certain factors that could make it more or less likely for a drug to be self-administered. *Id*. What these instructions and rebuttable presumptions constitute are determinations regarding the reasonableness and necessity of self-administration versus administration by a medical professional. At the motion to dismiss stage, these manual provisions and instructions support a plausible claim that the Secretary has misinterpreted the applicability of Medicare's statutory liability protections.

Further, as Plaintiffs alleged, Congress intended to protect beneficiaries from *unexpected* denials of coverage. It applied liability protections to denials based on services being "not reasonable and necessary" because beneficiaries are not medical experts and cannot be expected to know when an item or service is medically required. It exempted from protection denials that are not and never have

been covered. ER-27–29, ¶¶ 43–51 (citing legislative history). By interpreting the statute's protections to be inapplicable to Plaintiffs, the Secretary acts as if they were denied coverage for cosmetic surgery (a service that is never covered), and ignores the fact that in this situation the drugs were long covered by Part B and can still be covered by Part D. Plaintiffs' surprise denials of coverage were not what Congress intended to exempt from protection. The Secretary's interpretation thwarts the statute's purpose.

In a footnote, the district court stated that it was "not persuaded" that the self-administration determination is in practice a "reasonable and necessary" decision. ER-15–16, n.6. But the standard at this stage "is not that plaintiff's explanation must be true or even probable. The factual allegations of the complaint need only 'plausibly suggest an entitlement to relief.'" *Starr v. Baca*, 652 F.3d 1202, 1216-17 (9th Cir. 2011) (quoting *Iqbal*, 556 U.S. at 681). Rather than considering Plaintiffs' allegations in the light most favorable to them, the district court made a conclusory statement that it had not been persuaded, without explanation about why, for example, relying on "conditions related to the drug" is not a determination about whether self-administration is "reasonable and necessary." It erred in dismissing Plaintiffs' statutory claim.

CONCLUSION

For the foregoing reasons, this Court should reverse and remand the decision of the district court.

Date: September 25, 2024

Respectfully submitted,

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UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Form 17. Statement of Related Cases Pursuant to Circuit Rule 28-2.6

9th Cir. Case Number(s): 24-3528

The undersigned attorney or self-represented party states the following:

[X] I am unaware of any related cases currently pending in this court.

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[ ] I am aware of one or more related cases currently pending in this court. The case number and name of each related case and its relationship to this case are:

Signature: s/Alice Bers **Date:** September 25, 2024

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Form 8. Certificate of Compliance for Briefs

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This brief contains 13,879 words, including zero words manually counted in any visual images, and excluding the items exempted by FRAP 32(f). The brief's type size and typeface comply with FRAP 32(a)(5) and (6).

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[ ] is accompanied by a motion to file a longer brief pursuant to Cir. R. 32-2(a).

Signature: s/Alice Bers **Date:** September 25, 2024

ADDENDUM

ADDENDUM TABLE OF CONTENTS

42 U.S.C. §§ 405(g)–(h) (excerpts)

§ 405. Evidence, procedure, and certification for payments.

…

(g) Judicial review

Any individual, after any final decision of the Commissioner of Social Security made after a hearing to which he was a party, irrespective of the amount in controversy, may obtain a review of such decision by a civil action commenced within sixty days after the mailing to him of notice of such decision or within such further time as the Commissioner of Social Security may allow. Such action shall be brought in the district court of the United States for the judicial district in which the plaintiff resides, or has his principal place of business, or, if he does not reside or have his principal place of business within any such judicial district, in the United States District Court for the District of Columbia.

…

(h) Finality of Commissioner's decision

The findings and decision of the Commissioner of Social Security after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the Commissioner of Social Security shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the Commissioner of Social Security, or any officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under this subchapter.

42 U.S.C. § 1395x(s)(2)(A)

§1395x. Definitions

…

(s) Medical and other health services

The term "medical and other health services" means any of the following items or services:

…

(2)(A) services and supplies (including drugs and biologicals which are not usually self-administered by the patient) furnished as an incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills (or would have been so included but for the application of section 1395w-3b of this title);

42 U.S.C. §§ 1395pp(a)–(b)

§ 1395pp. Limitation on liability where claims are disallowed

(a) Conditions prerequisite to payment for items and services notwithstanding determination of disallowance

Where--

(1) a determination is made that, by reason of section 1395y(a)(1) or (9) of this title or by reason of a coverage denial described in subsection (g), payment may not be made under part A or part B of this subchapter for any expenses incurred for items or services furnished an individual by a provider of services or by another person pursuant to an assignment under section 1395u(b)(3)(B)(ii) of this title, and

(2) both such individual and such provider of services or such other person, as the case may be, did not know, and could not reasonably have been expected to know, that payment would not be made for such items or services under such part A or part B,

then to the extent permitted by this subchapter, payment shall, notwithstanding such determination, be made for such items or services (and for such period of time as the Secretary finds will carry out the objectives of this subchapter), as though section 1395y(a)(1) and section 1395y(a)(9) of this title did not apply and as though the coverage denial described in subsection (g) had not occurred. In each such case the Secretary shall notify both such individual and such provider of services or such other person, as the case may be, of the conditions under which payment for such items or services was made and in the case of comparable situations arising thereafter with respect to such individual or such provider or such other person, each shall, by reason of such notice (or similar notices provided before the enactment of this section), be deemed to have knowledge that payment cannot be made for such items or services or reasonably comparable items or services. Any provider or other person furnishing items or services for which payment may not be made by reason of section 1395y(a)(1) or (9) of this title or by reason of a coverage denial described in subsection (g) shall be deemed to have knowledge that payment cannot be made for such items or services if the claim relating to such items or services involves a case, provider or other person furnishing services, procedure, or test, with respect to which such provider or other person has been notified by the Secretary

(including notification by a quality improvement organization) that a pattern of inappropriate utilization has occurred in the past, and such provider or other person has been allowed a reasonable time to correct such inappropriate utilization.

(b) Knowledge of person or provider that payment could not be made; indemnification of individual

In any case in which the provisions of paragraphs (1) and (2) of subsection (a) are met, except that such provider or such other person, as the case may be, knew, or could be expected to know, that payment for such services or items could not be made under such part A or part B, then the Secretary shall, upon proper application filed within such time as may be prescribed in regulations, indemnify the individual (referred to in such paragraphs) for any payments received from such individual by such provider or such other person, as the case may be, for such items or services. Any payments made by the Secretary as indemnification shall be deemed to have been made to such provider or such other person, as the case may be, and shall be treated as overpayments, recoverable from such provider or such other person, as the case may be, under applicable provisions of law. In each such case the Secretary shall notify such individual of the conditions under which indemnification is made and in the case of comparable situations arising thereafter with respect to such individual, he shall, by reason of such notice (or similar notices provided before the enactment of this section), be deemed to have knowledge that payment cannot be made for such items or services. No item or service for which an individual is indemnified under this subsection shall be taken into account in applying any limitation on the amount of items and services for which payment may be made to or on behalf of the individual under this subchapter.

88 Fed. Reg. 52262, 52387 (Aug. 7, 2023) (excerpt)

Federal Register, Proposed Rules, Department of Health and Human Services, Centers for Medicare & Medicaid Services

Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies

…

2. Request for Information (RFI): Drugs and Biologicals Which Are Not Usually Self-Administered by the Patient, and Complex Drug Administration Coding.

Section 1861(s)(2)(A) of the Act allows Medicare to pay for services and supplies, including drugs and biologicals (hereafter, drugs) that are not usually self-administered by the patient, which are furnished as ''incident to'' a physician's professional service. Section 112 of the Benefits, Improvements & Protection Act of 2000 (BIPA) (Pub. L. 106–554, December 21, 2000) amended the above-referenced sections 1861(s)(2)(A) and 1861(s)(2)(B) of the Act, which formerly referred to drugs ''which cannot be self-administered,'' to read, ''which are not usually self-administered.'' Drugs that are ''usually self-administered'' are thus statutorily excluded from coverage and payment under Part B under the ''incident to'' benefit.

We have provided definitions and other guidance for MACs regarding determinations on drugs that are ''not usually self-administered by the patient'' in Chapter 15, Section 50.2 of the Medicare Benefit Policy Manual. Chapter 15 also describes the evidentiary criteria that MACs should use in determining whether a drug is usually self-administered. The guidance directs MACs to publish a description of the process they use to make that determination, and to publish a list of the drugs that are subject to the self-administered exclusion on their website. The guidance also requires that this list include the data and rationale that led to the determinations. This list is referred to as the ''self-administered drug (SAD) list,'' and each MAC maintains their own version of the list, which is applicable to that MAC's area of jurisdiction. While the lists are often similar between MACs, they are not identical. Drugs that are put on a SAD list are excluded from Part B coverage, but in those situations, they are almost always covered by Medicare Part D prescription drug coverage. For several years, interested parties have requested that we update and clarify this SAD list guidance. These parties believe that the current guidance may not adequately address circumstances posed by newly approved drugs.

Self-Administered Drug Exclusion List Article

Article - Self-Administered Drug Exclusion List: (A53032)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

NOT AN LCD REFERENCE ARTICLE

This article is not in direct support of an LCD. Learn more

Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
Noridian Healthcare Solutions, LLC	A and B MAC	01111 - MAC A	J - E	California - Entire State
Noridian Healthcare Solutions, LLC	A and B MAC	01112 - MAC B	J - E	California - Northern
Noridian Healthcare Solutions, LLC	A and B MAC	01182 - MAC B	J - E	California - Southern
Noridian Healthcare Solutions, LLC	A and B MAC	01211 - MAC A	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01212 - MAC B	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01311 - MAC A	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01312 - MAC B	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01911 - MAC A	J - E	American Samoa California - Entire State Guam Hawaii Nevada Northern Mariana Islands

Article Information

General Information

Article ID
A53032

Article Title
Self-Administered Drug Exclusion List:

Article Type
SAD Exclusion Article

Original Effective Date
10/01/2015

Revision Effective Date
07/01/2024

Revision Ending Date
N/A

Retirement Date
N/A

Article Guidance

Article Text

The following SAD list is current as of 06/23/2024. However, the Noridian Contractor Medical Directors (CMDs) review the list on an ongoing basis and may update and republish at their discretion.

The Medicare program provides limited benefits for outpatient prescription drugs. The program covers drugs that are furnished "incident-to" a physician's service provided that the drugs are not "usually self-administered" by the patient. Section 112 of the Benefits, Improvements & Protection Act of 2000 (BIPA), amended §§1861(s)(2)(A) and 1861(s)(2)(B) of the Social Security Act (SSA) to redefine this exclusion. The prior statutory language referred to those drugs "which cannot be self-administered by the patient." Implementation of the BIPA provision requires interpretation of the phrase "not usually self-administered" by the patient.

CMS has defined "not usually self-administered" by the patient, according to how the Medicare population as a whole uses the drug, not how an individual patient or physician may choose to use a particular drug. This is defined in the CMS Manual System, Pub 100-02, Medicare Benefit Policy Manual, Chapter 15, §50.2, Determining Self-

Administration of Drug or Biological.

For purpose of this exclusion, "the term 'usually' means more than 50 percent of the time for all Medicare beneficiaries who use the drug. Therefore, if a drug is self-administered by more than 50 percent of Medicare beneficiaries, the drug is excluded from coverage" and this A/B MAC will make no payment for the drug.

The term 'administered' refers only to the physical process by which the drug enters the patient's body. Injectable drugs, including intravenously administered drugs, are typically eligible for inclusion under the 'incident to' benefit. With limited exceptions, other routes of administration including, but not limited to, oral drugs, suppositories, topical medications are considered to be usually self-administered by the patient.

The term 'by the patient' means Medicare beneficiaries as a collective whole. The determination is based on whether the drug is self-administered by the patient the majority of the time. This determination is made on a drug-by-drug basis, not on a beneficiary-by-beneficiary basis.

Noridian is committed to assuring appropriate coverage for those drugs that meet Medicare statute requirements for drugs, "not usually self-administered by the patient."

In the absence of objective data specific to the Medicare beneficiary population who are capable of self-administration of an injectable drug, this A/B MAC will consider the following factors listed below, weighted on a per indication basis, to estimate, whether an injectable drug in the outpatient setting is "usually or not usually self-administered:"

1. **Route**: Intravenous (IV) route and Intramuscular (IM) route of administration will be presumed to meet "not usually self-administered" requirements and therefore meets Medicare benefit category. We may consider the depth and nature of the particular injection in applying this presumption. Subcutaneous (SQ) route of administration will not be presumed to meet the "not usually self-administered by the patient."

2. **Acuity of condition being treated**: In accordance with CMS instructions, if the condition being treated is for a short term acute basis (e.g. less than two weeks), the drug for this indication is considered "not usually self-administered." If the condition being treated is for a longer term (more than two weeks), the drug for this indication is considered "usually self-administered by the patient."

3. **Setting of condition being treated**: To the extent an injectable drug for a particular indication is given, e.g., only in an emergency department setting, pre-operative outpatient setting, or in the context of chemotherapy administration, the drug for that indication would be presumed to be for an acute situation and therefore "not usually self-administered."

4. **Frequency of administration**: In accordance with CMS instructions, if a drug is administered once per month, it is less likely to be self-administered by the patient. If a drug is administered once or more per week, it is likely that the drug is administered by the patient.

Process For Determining Benefit Category

To determine if a drug meets the definition of “usually self-administered” on a Medicare population basis, as required by CMS instructions, Noridian will use the following process:

Self-Administered Drug Process Flow

The process steps to determine whether a drug is self-administered are as follows:

- Determine if the drug is produced in parenteral form.
- Determine the route of administration. If the drug is only administered IV, the drug is a covered benefit.
- Determine if the route of administration is IM or SQ, and if the drug is administered in the outpatient setting, list the clinical indications and determine the percent of utilization by clinical indication.
- Review claims data and check a variety of sources/factors to arrive at the preliminary recommendation:

- Acute/chronic setting
- Clinical indication
- FDA/drug package inserts
- Provider specialty

- Estimate the percent self-administered (greater than or less than 50 percent) by indication.
- Assess all information to determine whether the drug is covered under the benefit category and notify providers.

If a drug meets the definition of "usually self-administered," Noridian will determine that the drug does not meet a Medicare benefit category. In this instance when the drug is administered "incident-to" the physician service, the provider may bill the beneficiary for the drug without an Advance Beneficiary Notice (ABN).

Consideration of Objective Evidence

In accordance with CMS instructions, Noridian will consider objective evidence when available to determine utilization of a particular drug.

Evidence

Noridian welcomes any data and evidence that describes utilization of injectable drugs in the outpatient setting, specific to the Medicare beneficiary population as outlined above.

Noridian is only required to consider the following types of evidence:

- Peer reviewed medical literature,
- Standards of medical practice,
- Evidence-based practice guidelines,
- FDA approved label, and
- Package inserts.

Noridian may also consider other evidence submitted by interested individuals or groups subject to their judgment.

Noridian will consider all of the information it receives in order to make a balanced and considered determination of benefit category meeting “not usually self-administered” injectable drugs. The information will be weighted according to the strength of the evidence.

General Information

These drugs have been deemed by this A/B MAC to be excluded from payment "incident-to" a physician's service because they are usually self-administered by the patients who take them.

The publication of this list begins a 45-day notice period. After the 45-day notice, this A/B MAC will deny payment for drugs subject to this notice. This list will be reviewed on a rolling basis and will be periodically updated as needed. Therefore, the absence of any particular drug on the exclusion list should not be taken to mean that at some later date the drug might be deemed excluded through application of the criteria referenced above.

Any miscellaneous HCPCS codes (J3490, J3590 and C9399) billed to Medicare for drugs that are listed in the Coding Table Information below will be denied.

For certain injectable drugs, it will be "apparent on its face" that the nature of the condition(s) for which they are administered, or the usual course of treatment for those conditions (chronic vs acute), in and of itself dictate the mode of usual administration. For example, a course of treatment consisting of scheduled injections lasting less than two weeks, regardless of frequency or route of administration, is considered by CMS as acute, and it would be unlikely that a patient would self-administer the drug in those circumstances [CMS Manual System, Pub 100-02, Medicare Benefit Policy Manual, Chapter 15, §50.2]

Basis for Non-Coverage

A. Apparent on its Face

B. Presumption: Long-Term Non-Acute Administration

C. Acceptable Evidentiary Criteria Available

Route of Administration Modifier

The use of the JA and JB modifiers is required for drugs which have one HCPCS Level II (J or Q) code but multiple routes of administration. Drugs that fall under this category will be marked with an asterisk (*) and must be billed with the JA modifier for the intravenous infusion of the drug or billed with the JB modifier for the subcutaneous injection form of administration. Absent evidence to the contrary, the Contractor presumes that drugs delivered intravenously are not usually self-administered by the patient. The Contractor will process claims with the JA modifier still applying the policy as stated in Medicare Benefit Policy Manual Chapter 15, section 50.2 that not only must the drug be medically reasonable and necessary, but also that the route of administration is medically reasonable and necessary. Subcutaneously administered drugs listed on the Usually Self-Administered list will be denied as a benefit exclusion. Claims for drugs marked with an asterisk (*) billed without either a JA or JB modifier will also be denied.

Note: The drugs represented by HCPCS codes J0801 and J0802 (marked with a double asterisk**) are administered by IM or SQ, therefore they require the JB modifier to be reported for SQ administration and they should not have any modifier reported for IM administration.

CPT/HCPCS Modifiers
Group 1 Paragraph: Claim denials may occur when the appropriate modifier is not applied to a J code/medication, which has more than one route of administration.
Group 1 Codes:

JA	Intravenous administration
JB	Subcutaneous administration

Providers are reminded that no form of insulin, regardless of route of administration including intravenous, intramuscular, subcutaneous, or inhalation, is reimbursable by Medicare. [This includes J8499: Insulin, inhaled (Exubera®), variable.]

If a beneficiary's claim for a particular drug is denied because the drug is subject to the "self-administered drug exclusion," the beneficiary may appeal the denial. Because it is a "benefit category" denial and not a denial based on medical necessity, an Advance Beneficiary Notice of Non-coverage (ABN) is not required. A "benefit category" denial (i.e., a denial based on the fact that there is no benefit category under which the drug may be covered) does not trigger the financial liability protection provisions of Limitation On Liability [under Section 1879 of the Act]. Therefore, physicians or providers may charge the beneficiary for such an excluded drug.

Provider and Physician Appeals

The hospital and a physician accepting assignment may appeal a denial under the provisions found in the IOM, Publication 100-04, Medicare Claims Processing Manual, Chapter 29, Section 200.

Reasonable and Necessary

Noridian will make the determination of reasonable and necessary with respect to the medical appropriateness of the drug to treat the patient's condition and will continue to make the determination of whether the intravenous or injection form of a drug is appropriate, as opposed to the oral form. We will also continue to make the determination as to whether a physician's office visit was reasonable and necessary. However, while a physician's office visit may not be reasonable and necessary in a specific situation, the medical necessity of the injection will still be determined on its own merits based on this process for determining which drugs are usually self-administered.

Sources
• IOM, Publication 100-02, Medicare Benefit Policy Manual, Chapter 15, Covered Medical and Other Health Services, Section 50.2, Determining Self-Administration of Drug or Biological
• Transmittal 123, CR 6950 dated April 30, 2010

Coding Information

ICD-10-CM Codes that Support Medical Necessity

Group 1 Paragraph:

N/A

Group 1 Codes:

N/A

ICD-10-CM Codes that DO NOT Support Medical Necessity

Group 1 Paragraph:

N/A

Group 1 Codes:

N/A

Additional ICD-10 Information

N/A

Bill Type Codes

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the article does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the article should be assumed to apply equally to all claims.

N/A

Revenue Codes

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the article, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the article should be assumed to apply equally to all Revenue Codes.

N/A

Coding Table Information

Excluded CPT/HCPCS Codes - Table Format

CODE	DESCRIPTOR GENERIC NAME	DESCRIPTOR BRAND NAME	EXCLUSION EFFECTIVE DATE	EXCLUSION END DATE	REASON FOR EXCLUSION
C9399	UNCLASSIFIED DRUGS OR BIOLOGICALS	Albiglutide for SQ injection	06/04/2015	N/A	Apparent on its Face|Presumption of Long-

CODE	DESCRIPTOR GENERIC NAME	DESCRIPTOR BRAND NAME	EXCLUSION EFFECTIVE DATE	EXCLUSION END DATE	REASON FOR EXCLUSION
		(Tanzeum™)			Term Non-Acute Administration
C9399	UNCLASSIFIED DRUGS OR BIOLOGICALS	Metreleptin for injection (Myalept ™)	06/04/2015	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
C9399	UNCLASSIFIED DRUGS OR BIOLOGICALS	Pasireotide (Signifor®)	06/04/2015	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
C9399	UNCLASSIFIED DRUGS OR BIOLOGICALS	Interferon beta 1a (Rebif ®)	06/04/2015	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
C9399	UNCLASSIFIED DRUGS OR BIOLOGICALS	Exenatide XR (Bydureon®)	06/04/2015	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
C9399	UNCLASSIFIED DRUGS OR BIOLOGICALS	Secukinumab (Cosentyx) subcutaneous use*	06/04/2015	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
C9399	UNCLASSIFIED DRUGS OR BIOLOGICALS	Alirocumab (Praluent®)	11/24/2015	N/A	Apparent on its Face
C9399	UNCLASSIFIED DRUGS OR BIOLOGICALS	Evolucumab (Repatha™)	11/24/2015	N/A	Apparent on its Face
C9399	UNCLASSIFIED DRUGS OR BIOLOGICALS	Dulaglutide (Trulicity®)	06/27/2016	N/A	Apparent on its Face
C9399	UNCLASSIFIED DRUGS OR BIOLOGICALS	Methotrexate - Solution Auto-injector Non Chemotherapeutic (Otrexup™, Rasuvo®)	06/27/2016	N/A	Apparent on its Face
C9399	UNCLASSIFIED DRUGS OR BIOLOGICALS	Parathyroid Hormone (Natpara®)	06/27/2016	N/A	Apparent on its Face
C9399	UNCLASSIFIED DRUGS OR BIOLOGICALS	Peginterferon beta-1a (Plegridy™)	06/27/2016	N/A	Apparent on its Face

CODE	DESCRIPTOR GENERIC NAME	DESCRIPTOR BRAND NAME	EXCLUSION EFFECTIVE DATE	EXCLUSION END DATE	REASON FOR EXCLUSION
C9399	UNCLASSIFIED DRUGS OR BIOLOGICALS	All insulin products	06/27/2016	N/A	Apparent on its Face
C9399	UNCLASSIFIED DRUGS OR BIOLOGICALS	Exenatide (Byetta®)	09/16/2013	N/A	Apparent on its Face
C9399	UNCLASSIFIED DRUGS OR BIOLOGICALS	Etanercept-SZZS (Erelzi™)	12/06/2016	N/A	Apparent on its Face
C9399	UNCLASSIFIED DRUGS OR BIOLOGICALS	Asfotase-alfa (Strensiq™)	02/28/2017	N/A	Apparent on its Face
C9399	UNCLASSIFIED DRUGS OR BIOLOGICALS	Ixekizumab (Taltz™)	02/28/2017	N/A	Apparent on its Face
C9399	UNCLASSIFIED DRUGS OR BIOLOGICALS	Adalimumab-atto (Amjevita™)	02/28/2017	N/A	Apparent on its Face
C9399	UNCLASSIFIED DRUGS OR BIOLOGICALS	Dupilumab (Dupixent)	08/07/2017	N/A	Apparent on its Face
C9399	UNCLASSIFIED DRUGS OR BIOLOGICALS	Brodalumab (Siliq)	08/07/2017	N/A	Apparent on its Face
C9399	UNCLASSIFIED DRUGS OR BIOLOGICALS	somapacitan-beco (Sogroya®)	04/05/2021	N/A	Apparent on its Face
C9399	UNCLASSIFIED DRUGS OR BIOLOGICALS	Ropeginterferon alfa-2b-njft (Besremi®)	04/24/2022	N/A	Apparent on its Face
C9399	UNCLASSIFIED DRUGS OR BIOLOGICALS	Risankizumab-rzaa (Skyrizi™) subcutaneous use*	05/15/2022	N/A	Presumption of Long-Term Non-Acute Administration|Acceptable Evidentiary Criteria Available
C9399	UNCLASSIFIED DRUGS OR BIOLOGICALS	ofatumumab (Kesimpta®) subcutaneous use*	07/17/2022	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
C9399	UNCLASSIFIED DRUGS OR BIOLOGICALS	tralokinumab-ldrm (Adbry™)	11/01/2022	N/A	Presumption of Long-Term Non-Acute Administration|Acceptable Evidentiary Criteria Available
C9399	UNCLASSIFIED DRUGS OR BIOLOGICALS	Tirzepatide (Mounjaro™, Zepbound)	11/19/2022	N/A	Apparent on its Face
C9399	UNCLASSIFIED DRUGS OR BIOLOGICALS	Adalimumab-aacf (Idacio®)	06/25/2023	N/A	Apparent on its Face

CODE	DESCRIPTOR GENERIC NAME	DESCRIPTOR BRAND NAME	EXCLUSION EFFECTIVE DATE	EXCLUSION END DATE	REASON FOR EXCLUSION
C9399	UNCLASSIFIED DRUGS OR BIOLOGICALS	Adalimumab-afzb (Abrilada™)	06/25/2023	N/A	Apparent on its Face
C9399	UNCLASSIFIED DRUGS OR BIOLOGICALS	Adalimumab-bwwd (Hadlima)	06/25/2023	N/A	Apparent on its Face
C9399	UNCLASSIFIED DRUGS OR BIOLOGICALS	Adalimumab-fkjp (Hulio®)	06/25/2023	N/A	Apparent on its Face
C9399	UNCLASSIFIED DRUGS OR BIOLOGICALS	Adalimumab-adaz (Hyrimoz)	06/25/2023	N/A	Apparent on its Face
C9399	UNCLASSIFIED DRUGS OR BIOLOGICALS	Adalimumab-aqvh (Yusimry)	06/25/2023	N/A	Apparent on its Face
C9399	UNCLASSIFIED DRUGS OR BIOLOGICALS	Vedolizumab (Entyvio®) subcutaneous use*	01/14/2024	N/A	Apparent on its Face
C9399	UNCLASSIFIED DRUGS OR BIOLOGICALS	Adalimumab-aaty (Yuflyma)	01/14/2024	N/A	Apparent on its Face
J0129	INJECTION, ABATACEPT, 10 MG (CODE MAY BE USED FOR MEDICARE WHEN DRUG ADMINISTERED UNDER THE DIRECT SUPERVISION OF A PHYSICIAN, NOT FOR USE WHEN DRUG IS SELF ADMINISTERED)	Orencia® subcutaneous use*	04/05/2021	N/A	Apparent on its Face
J0135	INJECTION, ADALIMUMAB, 20 MG	Humira®	09/16/2013	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J0270	INJECTION, ALPROSTADIL, 1.25 MCG (CODE MAY BE USED FOR MEDICARE WHEN DRUG ADMINISTERED UNDER THE DIRECT SUPERVISION OF A PHYSICIAN, NOT FOR USE WHEN DRUG IS SELF ADMINISTERED)	Alprostadil®, Caverject®, Edex®, Prostin VR Pediatric®	09/16/2013	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J0364	INJECTION, APOMORPHINE HYDROCHLORIDE, 1 MG	Apokyn®	06/04/2015	N/A	Apparent on its Face|Presumption of Long-

CODE	DESCRIPTOR GENERIC NAME	DESCRIPTOR BRAND NAME	EXCLUSION EFFECTIVE DATE	EXCLUSION END DATE	REASON FOR EXCLUSION
					Term Non-Acute Administration
J0593	INJECTION, LANADELUMAB-FLYO, 1 MG (CODE MAY BE USED FOR MEDICARE WHEN DRUG ADMINISTERED UNDER DIRECT SUPERVISION OF A PHYSICIAN, NOT FOR USE WHEN DRUG IS SELF-ADMINISTERED)	lanadelumab-flyo (TAKHZYRO)	12/02/2019	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J0599	INJECTION, C-1 ESTERASE INHIBITOR (HUMAN), (HAEGARDA), 10 UNITS	HAEGARDA®	09/18/2019	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J0630	INJECTION, CALCITONIN SALMON, UP TO 400 UNITS	Calcimar®, Miacalcin, Osteocalcin, Salmonine, Fortical	09/16/2013	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J0801	INJECTION, CORTICOTROPIN (ACTHAR GEL), UP TO 40 UNITS	H.P. Acthar® Gel subcutaneous use**	10/01/2023	N/A	Apparent on its Face
J0802	INJECTION, CORTICOTROPIN (ANI), UP TO 40 UNITS	H.P. Acthar® Gel subcutaneous use**	10/01/2023	N/A	Apparent on its Face
J1324	INJECTION, ENFUVIRTIDE, 1 MG	Fuzeon®	09/16/2013	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J1438	INJECTION, ETANERCEPT, 25 MG (CODE MAY BE USED FOR MEDICARE WHEN DRUG ADMINISTERED UNDER THE DIRECT SUPERVISION OF A PHYSICIAN, NOT FOR USE WHEN DRUG IS SELF ADMINISTERED)	Enbrel®	09/16/2013	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J1595	INJECTION, GLATIRAMER ACETATE, 20 MG	Copaxone®	09/16/2013	N/A	Apparent on its Face|Presumption of Long-

CODE	DESCRIPTOR GENERIC NAME	DESCRIPTOR BRAND NAME	EXCLUSION EFFECTIVE DATE	EXCLUSION END DATE	REASON FOR EXCLUSION
					Term Non-Acute Administration
J1628	INJECTION, GUSELKUMAB, 1 MG	guselkumab (Tremfya®)	05/15/2021	N/A	Acceptable Evidentiary Criteria Available
J1675	INJECTION, HISTRELIN ACETATE, 10 MICROGRAMS	Supprelin LA®	09/16/2013	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J1744	INJECTION, ICATIBANT, 1 MG	Icatibant (Firazyr®)	09/16/2013	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J1748	INJECTION, INFLIXIMAB-DYYB (ZYMFENTRA), 10 MG	Injection, infliximab-dyyb (zymfentra)	08/18/2024	N/A	Apparent on its Face
J1811	INSULIN (FIASP) FOR ADMINISTRATION THROUGH DME (I.E., INSULIN PUMP) PER 50 UNITS	Fiasp®	08/20/2023	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J1812	INSULIN (FIASP), PER 5 UNITS	Fiasp®	08/20/2023	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J1813	INSULIN (LYUMJEV) FOR ADMINISTRATION THROUGH DME (I.E., INSULIN PUMP) PER 50 UNITS	Lyumjev®	08/20/2023	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J1814	INSULIN (LYUMJEV), PER 5 UNITS	Lyumjev® 100 IU*	08/20/2023	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J1814	INSULIN (LYUMJEV), PER 5 UNITS	Lyumjev® 200 IU	08/20/2023	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J1815	INJECTION, INSULIN, PER 5 UNITS	All insulin products	09/16/2013	N/A	Apparent on its Face|Presumption of Long-

CODE	DESCRIPTOR GENERIC NAME	DESCRIPTOR BRAND NAME	EXCLUSION EFFECTIVE DATE	EXCLUSION END DATE	REASON FOR EXCLUSION
					Term Non-Acute Administration
J1817	INSULIN FOR ADMINISTRATION THROUGH DME (I.E., INSULIN PUMP) PER 50 UNITS	All insulin products	09/16/2013	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J1830	INJECTION, INTERFERON BETA-1B, 0.25 MG (CODE MAY BE USED FOR MEDICARE WHEN DRUG ADMINISTERED UNDER THE DIRECT SUPERVISION OF A PHYSICIAN, NOT FOR USE WHEN DRUG IS SELF ADMINISTERED)	Betaseron®	09/16/2013	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J1941	INJECTION, FUROSEMIDE (FUROSCIX), 20 MG	furosemide (Furoscix®)	08/20/2023	N/A	Apparent on its Face
J2170	INJECTION, MECASERMIN, 1 MG	Increlex®, Iplex	09/16/2013	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J2212	INJECTION, METHYLNALTREXONE, 0.1 MG	Relistor®	09/16/2013	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J2267	INJECTION, MIRIKIZUMAB-MRKZ, 1 MG	Mirikizumab-mrkz*	07/01/2024	N/A	Apparent on its Face
J2354	INJECTION, OCTREOTIDE, NON-DEPOT FORM FOR SUBCUTANEOUS OR INTRAVENOUS INJECTION, 25 MCG	Octreotide Acetate (Sandostatin)*	09/16/2013	N/A	Presumption of Long-Term Non-Acute Administration
J2440	INJECTION, PAPAVERINE HCL, UP TO 60 MG	Papaverine HCL	09/16/2013	N/A	Apparent on its Face
J2940	INJECTION, SOMATREM, 1 MG	Protropin®	09/16/2013	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration

CODE	DESCRIPTOR GENERIC NAME	DESCRIPTOR BRAND NAME	EXCLUSION EFFECTIVE DATE	EXCLUSION END DATE	REASON FOR EXCLUSION
J2941	INJECTION, SOMATROPIN, 1 MG	Humatrope, Genotropin, Omnitrope, (Saizen, Zorbtive, Zomacton, Norditropin, Nutropin)	09/16/2013	N/A	Presumption of Long-Term Non-Acute Administration|Acceptable Evidentiary Criteria Available
J3030	INJECTION, SUMATRIPTAN SUCCINATE, 6 MG (CODE MAY BE USED FOR MEDICARE WHEN DRUG ADMINISTERED UNDER THE DIRECT SUPERVISION OF A PHYSICIAN, NOT FOR USE WHEN DRUG IS SELF ADMINISTERED)	Imitrex®	09/16/2013	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J3031	INJECTION, FREMANEZUMAB-VFRM, 1 MG (CODE MAY BE USED FOR MEDICARE WHEN DRUG ADMINISTERED UNDER THE DIRECT SUPERVISION OF A PHYSICIAN, NOT FOR USE WHEN DRUG IS SELF-ADMINISTERED)	Fremanezumab-vfrm (Ajovy)	09/18/2019	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J3110	INJECTION, TERIPARATIDE, 10 MCG	Forteo®	09/16/2013	N/A	Presumption of Long-Term Non-Acute Administration
J3355	INJECTION, UROFOLLITROPIN, 75 IU	Metrodin®, Bravelle®, Fertinex®	09/16/2013	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J3357	USTEKINUMAB, FOR SUBCUTANEOUS INJECTION, 1 MG	Stelara®	10/15/2021	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J3490	UNCLASSIFIED DRUGS	mipomersen sodium (Kynamro®)	09/16/2013	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J3490	UNCLASSIFIED DRUGS	TriMix	09/16/2013	N/A	Apparent on its

CODE	DESCRIPTOR GENERIC NAME	DESCRIPTOR BRAND NAME	EXCLUSION EFFECTIVE DATE	EXCLUSION END DATE	REASON FOR EXCLUSION
					Face|Presumption of Long-Term Non-Acute Administration
J3490	UNCLASSIFIED DRUGS	Tesamorelin Acetate (Egrifta®)	09/16/2013	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J3490	UNCLASSIFIED DRUGS	Liraglutide GLP-1 (Victoza®, Saxenda®)	09/16/2013	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J3490	UNCLASSIFIED DRUGS	Pramlintide acetate (Symlin®, SymlinPen 60, SymlinPen 120)	09/16/2013	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J3490	UNCLASSIFIED DRUGS	Exenatide (Byetta®)	09/16/2013	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J3490	UNCLASSIFIED DRUGS	Peginterferon Alfa 2-b (Sylatron, Pegintron)	09/16/2013	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J3490	UNCLASSIFIED DRUGS	Albiglutide for SQ injection (Tanzeum™)	06/04/2015	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J3490	UNCLASSIFIED DRUGS	Metreleptin for injection (Myalept ™)	06/04/2015	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J3490	UNCLASSIFIED DRUGS	Pasireotide (Signifor®)	06/04/2015	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J3490	UNCLASSIFIED DRUGS	Interferon beta 1a, (Rebif®)	06/04/2015	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration

CODE	DESCRIPTOR GENERIC NAME	DESCRIPTOR BRAND NAME	EXCLUSION EFFECTIVE DATE	EXCLUSION END DATE	REASON FOR EXCLUSION
J3490	UNCLASSIFIED DRUGS	Exenatide XR (Bydureon®)	06/04/2015	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration|Acceptable Evidentiary Criteria Available
J3490	UNCLASSIFIED DRUGS	Secukinumab (Cosentyx) subcutaneous use*	06/04/2015	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J3490	UNCLASSIFIED DRUGS	All insulin products	09/18/2019	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J3490	UNCLASSIFIED DRUGS	Adalimumab-adbm (Cyltezo)	09/18/2019	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J3490	UNCLASSIFIED DRUGS	somapacitan-beco (Sogroya®)	04/05/2021	N/A	Apparent on its Face
J3490	UNCLASSIFIED DRUGS	Ropeginterferon alfa-2b-njft (Besremi®)	04/24/2022	N/A	Apparent on its Face
J3490	UNCLASSIFIED DRUGS	Risankizumab-rzaa (Skyrizi™) subcutaneous use*	05/15/2022	N/A	Presumption of Long-Term Non-Acute Administration|Acceptable Evidentiary Criteria Available
J3490	UNCLASSIFIED DRUGS	ofatumumab (Kesimpta®) subcutaneous use*	07/17/2022	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J3490	UNCLASSIFIED DRUGS	tralokinumab-ldrm (Adbry™)	11/01/2022	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J3490	UNCLASSIFIED DRUGS	Tirzepatide (Mounjaro™, Zepbound)	11/19/2022	N/A	Apparent on its Face
J3490	UNCLASSIFIED DRUGS	Adalimumab-aqvh (Yusimry)	06/25/2023	N/A	Apparent on its Face

CODE	DESCRIPTOR GENERIC NAME	DESCRIPTOR BRAND NAME	EXCLUSION EFFECTIVE DATE	EXCLUSION END DATE	REASON FOR EXCLUSION
J3490	UNCLASSIFIED DRUGS	Adalimumab-adaz (Hyrimoz)	06/25/2023	N/A	Apparent on its Face
J3490	UNCLASSIFIED DRUGS	Adalimumab-fkjp (Hulio®)	06/25/2023	N/A	Apparent on its Face
J3490	UNCLASSIFIED DRUGS	Adalimumab-bwwd (Hadlima)	06/25/2023	N/A	Apparent on its Face
J3490	UNCLASSIFIED DRUGS	Adalimumab-afzb (Abrilada™)	06/25/2023	N/A	Apparent on its Face
J3490	UNCLASSIFIED DRUGS	Adalimumab-aacf (Idacio®)	06/25/2023	N/A	Apparent on its Face
J3490	UNCLASSIFIED DRUGS	Adalimumab-aaty (Yuflyma)	01/14/2024	N/A	Apparent on its Face
J3490	UNCLASSIFIED DRUGS	Vedolizumab (Entyvio®) subcutaneous use*	01/14/2024	N/A	Apparent on its Face
J3590	UNCLASSIFIED BIOLOGICS	Vedolizumab (Entyvio®) subcutaneous use*	01/14/2024	N/A	Apparent on its Face
J3590	UNCLASSIFIED BIOLOGICS	Adalimumab-aaty (Yuflyma)	01/14/2024	N/A	Apparent on its Face
J3590	UNCLASSIFIED BIOLOGICS	Adalimumab-aacf (Idacio®)	06/25/2023	N/A	Apparent on its Face
J3590	UNCLASSIFIED BIOLOGICS	Adalimumab-afzb (Abrilada™)	06/25/2023	N/A	Apparent on its Face
J3590	UNCLASSIFIED BIOLOGICS	Adalimumab-bwwd (Hadlima)	06/25/2023	N/A	Apparent on its Face
J3590	UNCLASSIFIED BIOLOGICS	Adalimumab-fkjp (Hulio®)	06/25/2023	N/A	Apparent on its Face
J3590	UNCLASSIFIED BIOLOGICS	Adalimumab-adaz (Hyrimoz)	06/25/2023	N/A	Apparent on its Face
J3590	UNCLASSIFIED BIOLOGICS	Adalimumab-aqvh (Yusimry)	06/25/2023	N/A	Apparent on its Face
J3590	UNCLASSIFIED BIOLOGICS	Tirzepatide (Mounjaro™, Zepbound)	11/19/2022	N/A	Apparent on its Face
J3590	UNCLASSIFIED BIOLOGICS	tralokinumab-ldrm (Adbry™)	11/01/2022	N/A	Presumption of Long-Term Non-Acute

CODE	DESCRIPTOR GENERIC NAME	DESCRIPTOR BRAND NAME	EXCLUSION EFFECTIVE DATE	EXCLUSION END DATE	REASON FOR EXCLUSION
					Administration|Acceptable Evidentiary Criteria Available
J3590	UNCLASSIFIED BIOLOGICS	ofatumumab (Kesimpta®) subcutaneous use*	07/17/2022	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J3590	UNCLASSIFIED BIOLOGICS	Risankizumab-rzaa (Skyrizi™) subcutaneous use*	05/15/2022	N/A	Presumption of Long-Term Non-Acute Administration|Acceptable Evidentiary Criteria Available
J3590	UNCLASSIFIED BIOLOGICS	Ropeginterferon alfa-2b-njft (Besremi®)	04/24/2022	N/A	Apparent on its Face
J3590	UNCLASSIFIED BIOLOGICS	somapacitan-beco (Sogroya®)	04/05/2021	N/A	Apparent on its Face
J3590	UNCLASSIFIED BIOLOGICS	Abaloparatide (Tymlos)	09/18/2019	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J3590	UNCLASSIFIED BIOLOGICS	Sarilumab (Kevzara)	09/18/2019	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J3590	UNCLASSIFIED BIOLOGICS	Semaglutide (Ozempic, Wegovy)	09/18/2019	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J3590	UNCLASSIFIED BIOLOGICS	Erenumab-aoooe (Aimovig)	09/18/2019	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J3590	UNCLASSIFIED BIOLOGICS	Alcanezumab-gnlm (Emgality)	09/18/2019	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J3590	UNCLASSIFIED BIOLOGICS	Alirocumab (Praluent®)	11/24/2015	N/A	Apparent on its Face
J3590	UNCLASSIFIED BIOLOGICS	Evolucumab (Repatha™)	11/24/2015	N/A	Apparent on its Face

CODE	DESCRIPTOR GENERIC NAME	DESCRIPTOR BRAND NAME	EXCLUSION EFFECTIVE DATE	EXCLUSION END DATE	REASON FOR EXCLUSION
J3590	UNCLASSIFIED BIOLOGICS	Dulaglutide (Trulicity®)	06/27/2016	N/A	Apparent on its Face
J3590	UNCLASSIFIED BIOLOGICS	Methotrexate - Solution Auto-injector Non Chemotherapeutic (Otrexup™, Rasuvo®)	06/27/2016	N/A	Apparent on its Face
J3590	UNCLASSIFIED BIOLOGICS	Parathyroid Hormone (Natpara®)	06/27/2016	N/A	Apparent on its Face
J3590	UNCLASSIFIED BIOLOGICS	Peginterferon beta-1a (Plegridy™)	06/27/2016	N/A	Apparent on its Face
J3590	UNCLASSIFIED BIOLOGICS	All insulin products	06/27/2016	N/A	Apparent on its Face
J3590	UNCLASSIFIED BIOLOGICS	Pegvisomant (Somavert®, variable)	09/16/2013	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J3590	UNCLASSIFIED BIOLOGICS	Golimumab (Simponi®)	09/16/2013	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J3590	UNCLASSIFIED BIOLOGICS	Abatacept (Orencia®)	09/16/2013	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J3590	UNCLASSIFIED BIOLOGICS	Etanercept-SZZS (Erelzi™)	12/06/2016	N/A	Apparent on its Face
J3590	UNCLASSIFIED BIOLOGICS	Asfotase-alfa (Strensiq™)	02/28/2017	N/A	Apparent on its Face
J3590	UNCLASSIFIED BIOLOGICS	Ixekizumab (Taltz™)	02/28/2017	N/A	Apparent on its Face
J3590	UNCLASSIFIED BIOLOGICS	Adalimumab-atto (Amjevita™)	02/28/2017	N/A	Apparent on its Face
J3590	UNCLASSIFIED BIOLOGICS	Dupilumab (Dupixent)	08/07/2017	N/A	Apparent on its Face
J3590	UNCLASSIFIED BIOLOGICS	Peginterferon Alfa-2a (Pegasys™,	09/16/2013	N/A	Apparent on its Face|Presumption of Long-

CODE	DESCRIPTOR GENERIC NAME	DESCRIPTOR BRAND NAME	EXCLUSION EFFECTIVE DATE	EXCLUSION END DATE	REASON FOR EXCLUSION
		Roferon®-A)			Term Non-Acute Administration
J3590	UNCLASSIFIED BIOLOGICS	Anakinra (Kineret®)	09/16/2013	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J3590	UNCLASSIFIED BIOLOGICS	Brodalumab (Siliq)	08/07/2017	N/A	Apparent on its Face
J3590	UNCLASSIFIED BIOLOGICS	Secukinumab (Cosentyx) subcutaneous use*	06/04/2015	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J9212	INJECTION, INTERFERON ALFACON-1, RECOMBINANT, 1 MICROGRAM	Infergen®	09/16/2013	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J9213	INJECTION, INTERFERON, ALFA-2A, RECOMBINANT, 3 MILLION UNITS	Roferon®-A	09/16/2013	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J9216	INJECTION, INTERFERON, GAMMA 1-B, 3 MILLION UNITS	Actimmune®	09/16/2013	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J9218	LEUPROLIDE ACETATE, PER 1 MG	Leuprolide Acetate, Leuprolide Acetate Inj	09/16/2013	N/A	Presumption of Long-Term Non-Acute Administration|Acceptable Evidentiary Criteria Available
Q0515	INJECTION, SERMORELIN ACETATE, 1 MICROGRAM	Geref®	09/16/2013	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
Q3027	INJECTION, INTERFERON BETA-1A, 1 MCG FOR INTRAMUSCULAR USE	Avonex®, Avonex Pen®	06/04/2015	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
Q3028	INJECTION, INTERFERON BETA-1A, 1 MCG FOR SUBCUTANEOUS USE	Rebif®	06/04/2015	N/A	Apparent on its Face|Presumption of Long-Term Non-Acute Administration

CODE	DESCRIPTOR GENERIC NAME	DESCRIPTOR BRAND NAME	EXCLUSION EFFECTIVE DATE	EXCLUSION END DATE	REASON FOR EXCLUSION
Q5131	INJECTION, ADALIMUMAB-AACF (IDACIO), BIOSIMILAR, 20 MG	Adalimumab-aacf (Idacio®)	07/01/2023	N/A	Apparent on its Face
Q5132	INJECTION, ADALIMUMAB-AFZB (ABRILADA), BIOSIMILAR, 10 MG	Abrilada injection, adalimumab-afzb (abrilada)	01/01/2024	N/A	Apparent on its Face
Q5137	INJECTION, USTEKINUMAB-AUUB (WEZLANA), BIOSIMILAR, SUBCUTANEOUS, 1 MG	ustekinumab-auub (wezlana)	07/01/2024	N/A	Apparent on its Face

Non-Excluded CPT/HCPCS Ended Codes - Table Format

CODE	DESCRIPTOR GENERIC NAME	DESCRIPTOR BRAND NAME	EXCLUSION EFFECTIVE DATE	EXCLUSION END DATE	REASON FOR EXCLUSION
C9399	UNCLASSIFIED DRUGS OR BIOLOGICALS	Mirikizumab-mrkz (Omvoh™) subcutaneous use*	01/14/2024	06/30/2024	Apparent on its Face
C9399	UNCLASSIFIED DRUGS OR BIOLOGICALS	ustekinumab-auub* (Wezlana)	03/17/2024	06/30/2024	Apparent on its Face
C9399	UNCLASSIFIED DRUGS OR BIOLOGICALS	Daclizumab (Zinbryta™)	02/28/2017	02/18/2021	Apparent on its Face
C9399	UNCLASSIFIED DRUGS OR BIOLOGICALS	Tezspire™ (tezepelumab-ekko)	07/17/2022	07/17/2022	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J0275	ALPROSTADIL URETHRAL SUPPOSITORY (CODE MAY BE USED FOR MEDICARE WHEN DRUG ADMINISTERED UNDER THE DIRECT SUPERVISION OF A PHYSICIAN, NOT FOR USE WHEN DRUG IS SELF ADMINISTERED)	Muse®	09/16/2013	07/14/2017	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J1559	INJECTION, IMMUNE GLOBULIN (HIZENTRA), 100 MG	Hizentra®	09/16/2013	12/31/2020	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J1562	INJECTION, IMMUNE GLOBULIN	Immune	09/16/2013	07/14/2017	Apparent on its

CODE	DESCRIPTOR GENERIC NAME	DESCRIPTOR BRAND NAME	EXCLUSION EFFECTIVE DATE	EXCLUSION END DATE	REASON FOR EXCLUSION
	(VIVAGLOBIN), 100 MG	Globulin, Vivaglobin			Face|Presumption of Long-Term Non-Acute Administration
J1575	INJECTION, IMMUNE GLOBULIN/HYALURONIDASE, (HYQVIA), 100 MG IMMUNEGLOBULIN	Immune globulin	02/11/2016	07/25/2016	
J1628	INJECTION, GUSELKUMAB, 1 MG	Tremfya®	05/03/2020	05/03/2020	Acceptable Evidentiary Criteria Available
J2502	INJECTION, PASIREOTIDE LONG ACTING, 1 MG	Pasireotide long acting	02/11/2016	10/01/2016	Apparent on its Face
J2760	INJECTION, PHENTOLAMINE MESYLATE, UP TO 5 MG	Regitine	09/16/2013	07/14/2017	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J3357	USTEKINUMAB, FOR SUBCUTANEOUS INJECTION, 1 MG	Stelara® subcutaneous	05/03/2020	05/03/2020	Acceptable Evidentiary Criteria Available
J3490	UNCLASSIFIED DRUGS	Tezspire™ (tezepelumab-ekko)	07/17/2022	07/17/2022	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J3490	UNCLASSIFIED DRUGS	Mirikizumab-mrkz (Omvoh™) subcutaneous use*	01/14/2024	06/30/2024	Apparent on its Face
J3490	UNCLASSIFIED DRUGS	ustekinumab-auub* (Wezlana)	03/17/2024	06/30/2024	Apparent on its Face
J3590	UNCLASSIFIED BIOLOGICS	ustekinumab-auub* (Wezlana)	03/17/2024	06/30/2024	Apparent on its Face
J3590	UNCLASSIFIED BIOLOGICS	Mirikizumab-mrkz (Omvoh™) subcutaneous use*	01/14/2024	06/30/2024	Apparent on its Face
J3590	UNCLASSIFIED BIOLOGICS	Tezspire™ (tezepelumab-ekko)	07/17/2022	07/17/2022	Apparent on its Face|Presumption of Long-Term Non-

CODE	DESCRIPTOR GENERIC NAME	DESCRIPTOR BRAND NAME	EXCLUSION EFFECTIVE DATE	EXCLUSION END DATE	REASON FOR EXCLUSION
					Acute Administration
J3590	UNCLASSIFIED BIOLOGICS	Efalizumab, Raptiva	09/16/2013	07/14/2017	Apparent on its Face|Presumption of Long-Term Non-Acute Administration
J3590	UNCLASSIFIED BIOLOGICS	Daclizumab (Zinbryta™)	02/16/2017	02/18/2021	Apparent on its Face
J3590	UNCLASSIFIED BIOLOGICS	risankizumab-rzaa (Skyrizi™)	12/02/2019	12/02/2019	Apparent on its Face|Presumption of Long-Term Non-Acute Administration

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
07/01/2024	R38	Revision Effective Date: 06/04/2015 EXCLUDED CPT/HCPCS CODES: Added: J3590 Secukinumab (Cosentyx) subcutaneous use* 09/12/2024: At this time 21st Century Cures Act applies to new and revised LCDs which require comment and notice. This revision is to an article that is not a local coverage determination.
07/01/2024	R37	The article has been updated due to a clerical error in the previous revision. The article has been updated to add a new code (Q5137) for Ustekinumab-auub (Wezlana) effective for dates of service on or after 7/1/2024.
07/01/2024	R36	The article has been updated to add a new code (Q5137) for Ustekinumab-auub (Wezlana) effective for dates of service on or after 7/1/2024. The previous miscellaneous codes C9399, J3490, and J3590 have been deleted. A new code (J2267) for Mirikizumab-mrkz* has been added effective for dates of service on or after 7/1/2024. The previous miscellaneous codes C9399, J3490, and J3590 have been deleted. The new drug code (J1748) Infliximab-dyyb (Zymfentra) has been added to SAD list

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
		with effective for dates of service on or after 8/18/2024.
06/16/2024	R35	The article has been updated to add brand names to the SAD list under their respective generic names for the following drugs: Semaglutide: Ozempic, Wegovy Tirzepatide: Mounjaro™, Zepbound The addition of the above mentioned brand names is effective 06/16/2024. The article has also been updated to apply consistent formatting for drug names. The new format applied is "generic name (brand name)". This formatting update does not change any coverage or guidance.
04/01/2024	R34	Added a double asterisk for J0801 and J0802. Under Article Text section added the following: NOTE: the drugs represented by HCPCS codes J0801 and J0802 (marked with a double asterisk**) are administered by IM or SQ, therefore they require the JB modifier to be reported for the SQ administration and they should not have any modifier reported for IM administration.
03/17/2024	R33	The article has been updated to add: Q5132 Abrilada (injection, adalimumab-afzb (abrilada) and should be used in place of the 3 miscellaneous codes effective for dates of service on and after 01/01/2024. Wezlana (ustekinumab-auub)* has been added for codes C9399, J3490, and J3590 effective for dates of service on and after 03/17/2024.
11/30/2023	R32	The article has been updated to add "subcutaneous use*" for HCPCS codes J0801, J0802 and for Secukinumab (Cosentyx™) (C9399, J3590). The following new drugs have been added: Vedolizumab (Entyvio®) subcutaneous use* (C9399, J3490, J3590), Adalimumab-aaty (Yuflyma) (C9399, J3490, J3590) and Mirikizumab-mrkz (Omvoh™) subcutaneous use* (C9399, J3490, J3590) effective for dates of service on or after 1/14/2024.
10/01/2023	R31	This article has been updated to delete: J0800 and was replaced with J0801 and J0802 effective 10/01/2023.

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
08/20/2023	R30	This article has been updated to add: J1811 insulin (Fiasp®), J1812 insulin (Fiasp®), J1813 insulin (Lyumjev®), J1814 (Lyumjev®) 100 IU*, J1814 (Lyumjev®) 200 IU, and J1941 furosemide (Furoscix®) effective for dates of service on or after 08/20/2023. Q5131 Adalimumab-aacf (Idacio®) effective for dates of service on or after 07/01/2023
06/25/2023	R29	The article has been updated to add: Adalimumab-aacf (Idacio®), Adalimumab-afzb (Abrilada™), Adalimumab-bwwd (Hadlima), Adalimumab-fkjp (Hulio®), Adalimumab-adaz (Hyrimoz), Adalimumab-aqvh (Yusimry) (C9399, J3490, J3590) effective for dates of service on or after 06/25/2023.
11/19/2022	R28	Under **Excluded CPT/HCPCS Codes** added: Mounjaro™ (Tirzepatide) - C9399, J3490, J3590 effective 11/19/2022. Under **Excluded CPT/HCPCS Codes** updated: **Descriptor Brand Names** for insulin products, the verbiage has been revised to read "All insulin products" for HCPCS codes C9399, J1815, J1817, J3490 and J3590.
11/01/2022	R27	The article is updated to add: Adbry™ (tralokinumab-ldrm) - C9399, J3490, J3590 effective 11/01/2022.
08/11/2022	R26	The article is updated to remove: Tezspire™ (tezepelumab-ekko) - C9399, J3490, J3590 effective 07/17/2022. *Note: J2356 assigned to Tezspire™ (tezepelumab-ekko) was also not added due to the removal. The article is updated to add an asterisk to Skyrizi™ - C9399, J3490, J3590 as this drug has multiple routes of administration and must be billed with the appropriate modifier. - Effective 06/17/2022.
07/17/2022	R25	The article is updated to add: Kesimpta® (ofatumumab) subcutaneous use* - C9399, J3490, J3590 effective 07/17/2022. The article is updated to add: Tezspire™ (tezepelumab-ekko) - C9399, J3490, J3590 effective 07/17/2022. Note: Effective July 1, 2022 - J2356 will be established and added to this article for Tezspire™ (tezepelumab-ekko) and should be used in place of the 3 miscellaneous

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
		codes in this revision.
05/15/2022	R24	The article is updated to add: Risankizumab-rzaa (Skyrizi™) - C9399, J3490, J3590 effective 05/15/2022.
04/24/2022	R23	The article updated to add: Ropeginterferon alfa-2b-njft (Besremi®) (C9399, J3490, J3590) effective 04/24/2022.
10/15/2021	R22	The "Route of Administrative Modifier" paragraph is revised. The drug J3357 Ustekinumab, for subcutaneous injection, 1 mg is added with an effective excluded date of 10/15/2021.
05/15/2021	R21	The article is updated to add: J1628, Injection, Guselkumab, (Tremfya®)1mg, effective 5/15/2021. The asterisk does not apply to J3357 and therefore has been removed.
04/05/2021	R20	The article is updated to add: J0129 (Orencia®, subcutaneous use*), C9399.J3490 and J3590 Sogroya® (somapacitan-beco), effective 4/5/2021. Removed the following drug to the Non-Excluded CPT/HCPCS Codes - Table Format: C9399 and J3590, Zinbryta (daclizumab), effective 2/18/2021. This drug was taken of the market. J2354 has been updated to add asterisk criteria in the "Descriptor Brand Name" section. Added the following in Article Guidance: **Route of Administration Modifier** The use of the JA and JB modifiers is required for drugs which have one HCPCS Level II (J or Q) code but multiple routes of administration. Drugs that fall under this category will be marked with an asterisk (*) and must be billed with JA modifier for the intravenous infusion of the drug or billed with the JB modifier for subcutaneous injection of the drug. Claims billed with the JA modifier are not part of the SAD exclusion. The Contractor will process claims with the JA modifier applying the policy that not only the drug is medically reasonable and necessary, but also that the route of administration is

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		medically reasonable and necessary. Claims for drugs marked with an asterisk (*) billed without a JA or JB modifier will be denied. **CPT/HCPCS Modifiers** **Group 1 Paragraph:** Claim denials may occur when the appropriate modifier is not applied to a J code/medication, which has more than one route off administration. **Group 1 Codes:** JA Intravenous administration JB Subcutaneous administration
01/01/2021	R19	Based on Transmittal 10463 (CR11880) (Billing for Home Infusion Therapy Services On or After January 1, 2021), which includes changes to the Medicare home infusion therapy services benefit, the article has been updated to move Hizentra® (J1559) to the Non-Excluded CPT/HCPCS Codes-Table with an Exclusion End Date of 12/31/2020.
05/03/2020	R18	The effective date of 5/3/2020 for Guselkumab (Tremfya®) (J1628) and Ustekinumab (Stelara®) (J3357) will be deferred to 45 days after the public health emergency ends. A notice article will be posted to Latest Update for the new effective date.
05/03/2020	R17	The following drugs are added to the SAD list with an effective date of 05/03/2020: J1628 - Injection, Guselkumba, 1mg, (Tremfya®) J3357 - Ustekinumab, for subcutaneous injection, 1 mg (Stelara®)
12/02/2019	R16	Due to the receipt of additional information and evidence-based literature, at this time the status of risankizumab-rzaa (Skyrizi) placement on the SAD List will be held pending further review.
12/02/2019	R15	This revision changes fremanezumab-vfrm (Ajovy) from code J3590 to code J3031, effective 10/01/2019. Code J3590 is effective from 09/18/2019 to 09/30/2019. This revision also adds the following drugs to the SAD exclusion list with an effective

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		date of 12/2/2019: J0593 - lanadelumab-flyo (TAKHZYRO) J3590 - risankizumab-rzaa (Skyrizi™) Also, Rebif® was added to the Descriptor Brand Name field for Q3028 and the spelling of Exenatide was corrected from Exanatide.
09/18/2019	R14	This revision updates the effective date of the drugs listed in Revision 13 from 09/09/2019 to 09/18/2019 to give providers the 45-day notice.
09/09/2019	R13	The following drugs are added to the SAD list with an effective date of 09/09/2019: J0599 – HAEGARDA J3490 – Insulin Glargin (recombinant), Lantus Solostar, Adalimumab-adbm (Cyltezo) J3590 - Abaloparatide (Tymlos), Sarilumab (Kevzara), Semaglutide (Ozempic), Fremanezumab-vfrm (Ajovy), Erenumab-aoooe (Aimovig), Alcanezumab-gnlm (Emgality)
08/07/2017	R12	The article is revised to remove the following drugs from the SAD list effective 7/14/2017: J0275, J1562, J2760 and J3590 (Efalizumab (Raptiva). The following drugs are added to the SAD list with an effective date of August 7, 2017: J3590, C9399 - Dupilumab (Dupixent) J3590, C9399 - Brodalumab (Siliq)
02/28/2017	R11	The article is revised to change the effective date of service from 2/6/2017 to 2/28/2017 for the following drugs: Asfotase-alfa (Strensiq™), Daclizumab (ZINBRYTA™), Ixekizumab (Taltz™), Adalimumab-atto (Amjevita™)

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
02/06/2017	R10	The article is revised to add the HCPCS codes J3590 and C9399 for the following drugs effective 2/6/2017. Asfotase-alfa (Strensiq™), Daclizumab (ZINBRYTA™), Ixekizumab (Taltz™), Adalimumab-atto (Amjevita™)
12/06/2016	R9	J2502 removed from the SAD list with an exclusion end date of 10/1/2016.
12/06/2016	R8	Added HCPCS Codes J3590, C9399 for Etanercept-SZZS (Erelzi™) effective 12/6/2016. Added Saxenda® brand name to include in HCPCS code J3490 Liraglutide GLP-1, Victoza®. The effective date remains 09/16/2013.
07/25/2016	R7	The article revised to remove HCPCS code J1575 from the excluded table with an effective date 7/25/2016.
06/27/2016	R6	The article is revised to add the following drugs effective 6/27/2016: Dulaglutide, Trulicity® (C9399, J3590), Methotrexate - Solution Auto-injector Non Chemotherapeutic, Otrexup™, Rasuvo® (C9399, J3590), Parathyroid Hormone, Natpara® (C9399, J3590), Peginterferon beta-1a, Plegridy™ (C9399, J3590), Insulin glargine injection, Toujeo® (C9399, J3590) and exanatide (Byetta®), variable (C9399). The sentence "Any miscellaneous HCPCS codes (J3490, J3590 and C9399) billed to Medicare for drugs that are listed in the Coding Table Information below will be denied" is added under the "General Information" in the Article Text section. This revised article, effective 6/27/2016 combines JE A A53031 into the JE B article so that both JEA and JEB contract numbers will have the same final Article number.
02/11/2016	R5	The article is revised to add J2502 and J1575 effective 2/11/2016.
11/24/2015	R4	The article is revised only to correct the effective date noted in R3 with effective date 11/18/2014. The correct effective date to deny J3590 or C9399 - Praluent® (Alirocumab) and J3590 or C9399 - Repatha™ (Evolucumab) is 11/24/2015.
11/24/2015	R3	The article is revised to add the following drugs to the SAD Exclusion List: J3590 or C9399 - Praluent® (Alirocumab) J3590 or C9399 - Repatha™ (Evolucumab) Effective 11/18/2015.
10/01/2015	R2	This article is revised with an effective date of 06/04/2015 for the HCPCS code J0364, and the following miscellaneous C9399 and J3490 HCPCS codes C9399 and J3490 for Albiglutide for SQ injection (Tanseum™), C9399 and J3490 for Metreleptin for injection, (Myalept™), C9399 and J3490 for Pasireotide (Signifor®), C9399 and J3490 for Interferon beta 1a, (Rebif®), C9399 and J3490 for Exenatide extended release (Bydureon ™) and C9399 and J3490 for Cosentyx (Secukinumab) from the SAD exclusion list. . For HCPCS codes Q3027 and Q3028, the correct effective date of service is also 06/04, 2015.
10/01/2015	R1	The article is revised to add the correct URL link to the Self Administered Drug Process.

Associated Documents

Medicare BPM Ch 15.50.2 SAD Determinations

Medicare BPM Ch 15.50.2

Related Local Coverage Documents

N/A

Related National Coverage Documents

N/A

SAD Process URL 1

http://med.noridianmedicare.com/web/jeb/policies/sads

SAD Process URL 2

N /A

Statutory Requirements URLs

N/A

Rules and Regulations URLs

N/A

CMS Manual Explanations URLs

N/A

Other URLs

N/A

Public Versions

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09/05/2024	07/01/2024 - N/A	Currently in Effect (This Version)
07/12/2024	07/01/2024 - N/A	Superseded
06/26/2024	07/01/2024 - N/A	Superseded
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03/29/2024	04/01/2024 - 06/22/2024	Superseded
01/23/2024	03/17/2024 - 03/31/2024	Superseded
11/22/2023	11/30/2023 - 03/16/2024	Superseded
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Keywords

- SAD
- Self Administered Drugs Exclusion List
- Self-Administered

Medicare Benefit Policy Manual, Pub. 100-02, Ch. 15 § 50.2

50.2 - Determining Self-Administration of Drug or Biological (Rev. 123, Issued: 04-30-10, Effective: 07-30-10, Implementation: 07-30-10)

The Medicare program provides limited benefits for outpatient prescription drugs. The program covers drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them. Section 112 of the Benefits, Improvements & Protection Act of 2000 (BIPA) amended sections 1861(s)(2)(A) and 1861(s)(2)(B) of the Act to redefine this exclusion. The prior statutory language referred to those drugs "which cannot be self-administered." Implementation of the BIPA provision requires interpretation of the phrase "not usually self-administered by the patient".

A. Policy

Fiscal intermediaries, carriers and Medicare Administrative Contractors (MACs) are instructed to follow the instructions below when applying the exclusion for drugs that are usually self-administered by the patient. Each individual contractor must make its own individual determination on each drug. Contractors must continue to apply the policy that not only the drug is medically reasonable and necessary for any individual claim, but also that the route of administration is medically reasonable and necessary. That is, if a drug is available in both oral and injectable forms, the injectable form of the drug must be medically reasonable and necessary as compared to using the oral form.

For certain injectable drugs, it will be apparent due to the nature of the condition(s) for which they are administered or the usual course of treatment for those conditions, they are, or are not, usually self-administered. For example, an injectable drug used to treat migraine headaches is usually self-administered. On the other hand, an injectable drug, administered at the same time as chemotherapy, used to treat anemia secondary to chemotherapy is not usually self-administered.

B. Administered

The term "administered" refers only to the physical process by which the drug enters the patient's body. It does not refer to whether the process is supervised by a medical professional (for example, to observe proper technique or side-effects of the drug). Injectable drugs, including intravenously administered drugs, are typically eligible for inclusion under the "incident to" benefit. With limited

exceptions, other routes of administration including, but not limited to, oral drugs, suppositories, topical medications are considered to be usually self-administered by the patient.

C. Usually

For the purposes of applying this exclusion, the term "usually" means more than 50 percent of the time for all Medicare beneficiaries who use the drug. Therefore, if a drug is self-administered by more than 50 percent of Medicare beneficiaries, the drug is excluded from coverage and the contractor may not make any Medicare payment for it. In arriving at a single determination as to whether a drug is usually self-administered, contractors should make a separate determination for each indication for a drug as to whether that drug is usually self-administered.

After determining whether a drug is usually self-administered for each indication, contractors should determine the relative contribution of each indication to total use of the drug (i.e., weighted average) in order to make an overall determination as to whether the drug is usually self-administered. For example, if a drug has three indications, is not self-administered for the first indication, but is self administered for the second and third indications, and the first indication makes up 40 percent of total usage, the second indication makes up 30 percent of total usage, and the third indication makes up 30 percent of total usage, then the drug would be considered usually self-administered.

Reliable statistical information on the extent of self-administration by the patient may not always be available. Consequently, CMS offers the following guidance for each contractor's consideration in making this determination in the absence of such data:

1. Absent evidence to the contrary, presume that drugs delivered intravenously are not usually self-administered by the patient.

2. Absent evidence to the contrary, presume that drugs delivered by intramuscular injection are not usually self-administered by the patient. (Avonex, for example, is delivered by intramuscular injection, not usually self-administered by the patient.) The contractor may consider the depth and nature of the particular intramuscular injection in applying this presumption. In applying this presumption, contractors should examine the use of the particular drug and consider the following factors:

3. Absent evidence to the contrary, presume that drugs delivered by subcutaneous injection are self-administered by the patient. However, contractors should examine the use of the particular drug and consider the following factors:

   A. **Acute Condition** - Is the condition for which the drug is used an acute condition? If so, it is less likely that a patient would self-administer the drug. If the condition were longer term, it would be more likely that the patient would self-administer the drug.

   B. **Frequency of Administration** - How often is the injection given? For example, if the drug is administered once per month, it is less likely to be self-administered by the patient. However, if it is administered once or more per week, it is likely that the drug is self-administered by the patient.

In some instances, carriers may have provided payment for one or perhaps several doses of a drug that would otherwise not be paid for because the drug is usually self-administered. Carriers may have exercised this discretion for limited coverage, for example, during a brief time when the patient is being trained under the supervision of a physician in the proper technique for self-administration. Medicare will no longer pay for such doses. In addition, contractors may no longer pay for any drug when it is administered on an outpatient emergency basis, if the drug is excluded because it is usually self-administered by the patient.

D. Definition of Acute Condition

For the purposes of determining whether a drug is usually self-administered, an acute condition means a condition that begins over a short time period, is likely to be of short duration and/or the expected course of treatment is for a short, finite interval. A course of treatment consisting of scheduled injections lasting less than 2 weeks, regardless of frequency or route of administration, is considered acute. Evidence to support this may include Food and Drug administration (FDA) approval language, package inserts, drug compendia, and other information.

E. By the Patient

The term “by the patient” means Medicare beneficiaries as a collective whole. The carrier includes only the patients themselves and not other individuals (that is, spouses, friends, or other care-givers are not considered the patient). The

determination is based on whether the drug is self-administered by the patient a majority of the time that the drug is used on an outpatient basis by Medicare beneficiaries for medically necessary indications. The carrier ignores all instances when the drug is administered on an inpatient basis.

The carrier makes this determination on a drug-by-drug basis, not on a beneficiary-by-beneficiary basis. In evaluating whether beneficiaries as a collective whole self-administer, individual beneficiaries who do not have the capacity to self-administer any drug due to a condition other than the condition for which they are taking the drug in question are not considered. For example, an individual afflicted with paraplegia or advanced dementia would not have the capacity to self-administer any injectable drug, so such individuals would not be included in the population upon which the determination for self-administration by the patient was based. Note that some individuals afflicted with a less severe stage of an otherwise debilitating condition would be included in the population upon which the determination for "self-administered by the patient" was based; for example, an early onset of dementia.

F. Evidentiary Criteria

Contractors are only required to consider the following types of evidence: peer reviewed medical literature, standards of medical practice, evidence-based practice guidelines, FDA approved label, and package inserts. Contractors may also consider other evidence submitted by interested individuals or groups subject to their judgment.

Contractors should also use these evidentiary criteria when reviewing requests for making a determination as to whether a drug is usually self-administered, and requests for reconsideration of a pending or published determination.

Note that prior to August 1, 2002, one of the principal factors used to determine whether a drug was subject to the self-administered exclusion was whether the FDA label contained instructions for self-administration. However, CMS notes that under the new standard, the fact that the FDA label includes instructions for self-administration is not, by itself, a determining factor that a drug is subject to this exclusion.

G. Provider Notice of Noncovered Drugs

Contractors must describe on their Web site the process they will use to determine whether a drug is usually self-administered and thus does not meet the "incident to" benefit category. Contractors must publish a list of the injectable drugs that are subject to the self-administered exclusion on their Web site, including the data and rationale that led to the determination. Contractors will report the workload associated with developing new coverage statements in CAFM 21208. Contractors must provide notice 45 days prior to the date that these drugs will not be covered. During the 45-day time period, contractors will maintain existing medical review and payment procedures. After the 45-day notice, contractors may deny payment for the drugs subject to the notice. Contractors must not develop local coverage determinations (LCDs) for this purpose because further elaboration to describe drugs that do not meet the 'incident to' and the 'not usually self-administered' provisions of the statute are unnecessary. Current LCDs based solely on these provisions must be withdrawn. LCDs that address the self-administered exclusion and other information may be reissued absent the self-administered drug exclusion material. Contractors will report this workload in CAFM 21206. However, contractors may continue to use and write LCDs to describe reasonable and necessary uses of drugs that are not usually self-administered.

H. Conferences Between Contractors

Contractors' Medical Directors may meet and discuss whether a drug is usually self-administered without reaching a formal consensus. Each contractor uses its discretion as to whether or not it will participate in such discussions. Each contractor must make its own individual determinations, except that fiscal intermediaries may, at their discretion, follow the determinations of the local carrier with respect to the self-administered exclusion.

I. Beneficiary Appeals

If a beneficiary's claim for a particular drug is denied because the drug is subject to the "self-administered drug" exclusion, the beneficiary may appeal the denial. Because it is a "benefit category" denial and not a denial based on medical necessity, an Advance Beneficiary Notice (ABN) is not required. A "benefit category" denial (i.e., a denial based on the fact that there is no benefit category under which the drug may be covered) does not trigger the financial liability protection provisions of Limitation On Liability (under §1879 of the Act).

Therefore, physicians or providers may charge the beneficiary for an excluded drug.

J. Provider and Physician Appeals

A physician accepting assignment may appeal a denial under the provisions found in Chapter 29 of the Medicare Claims Processing Manual.

K. Reasonable and Necessary

Contractors will make the determination of reasonable and necessary with respect to the medical appropriateness of a drug to treat the patient's condition. Contractors will continue to make the determination of whether the intravenous or injection form of a drug is appropriate as opposed to the oral form. Contractors will also continue to make the determination as to whether a physician's office visit was reasonable and necessary. However, contractors should not make a determination of whether it was reasonable and necessary for the patient to choose to have his or her drug administered in the physician's office or outpatient hospital setting. That is, while a physician's office visit may not be reasonable and necessary in a specific situation, in such a case an injection service would be payable.

L. Reporting Requirements

Each carrier, intermediary and Medicare Administrative Contractor (MAC) must report to CMS its complete list of injectable drugs that the contractor has determined are excluded when furnished incident to a physician's service on the basis that the drug is usually self-administered. The CMS expects that contractors will review injectable drugs on a rolling basis and update their list of excluded drugs as it is developed and no less frequently than annually. For example, contractors should not wait to publish this list until every drug has been reviewed. Contractors must enter their self-administered drug exclusion list to the Medicare Coverage Database (MCD). This database can be accessed at www.cms.hhs.gov/mcd. See Pub.100-08, Medicare Program Integrity Manual, Chapter 3, Section 3.3, "Articles", for instructions on submitting these lists to the MCD.

U.S. Constitution
Amendment V

No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury, except in cases arising in the land or naval forces, or in the Militia, when in actual service in time of War or public danger; nor shall any person be subject for the same offence to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation.